EFFECTIVENESS OF LEG MASSAGE ON PHYSIOLOGICAL LOWER LEG EDEMA AMONG ANTENATAL MOTHERS ADMITTED AT SELECTED HOSPITALS, COIMBATORE

By

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“It is health that is real wealth and not pieces of gold and silver.”

Mahatma Gandhi

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ABSTRACT

Effectiveness of leg massage on physiological lower leg edema among antenatal mothers admitted at selected hospital , Coimbatore

Background of the study: Pregnancy is presumed to be a major contributory factor in the increased incidence of varicose veins in women, which in turn lead to venous insufficiency and leg edema. Edema occurs when body fluids increase to nurture both mother and her baby and accumulate in the tissues as a result of increased blood flow and pressure of the growing uterus on the pelvic veins and the vena cava. In recent years, there has been an increased acceptance of the use of complementary therapies within the healthcare system. Leg massage is an example of an intervention that can be used for specific conditions such as leg and foot edema as it moves extravascular fluid without disturbing intravascular fluid.

Objective: The main objective of the study was to assess the effectiveness of leg massage in reduction of degree of physiological lower leg edema among antenatal mothers.

Methods: The research design adopted was Pre experimental one group pre test post test design. The sample size was 40 antenatal mothers with physiological lower leg edema in PSG Hospitals. Convenient sampling technique was used in this study. Those who fulfilled the inclusion criteria were selected for this study. The risk factors of physiological lower leg edema was assessed by questionnaire. Pre test was done using modified Erwin edema tool. Intervention of leg massage was given for 20minutes in each leg and post test assessment was done after 6hours of intervention till discharge.

Result of the study: The post-test day1 mean value (8.65) , post test day 2 mean value (6.15) and post test day3 mean value (4.60) were lower than the pre-test mean value (10.7) and post test day 3 and day2 values were lower than post test day1 mean value. The obtained paired't' test values (19.69) are higher than the tabulated value (1.68) ($P<0.05$) was highly significant. Post test day1 revealed that among 40 antenatal mothers, 2 mothers (5%) had mild edema, 36mothers (90%) had moderate edema, 2mothers (5%) had severe edema. Post test day2 revealed that 27mothers (67.5%) had mild edema, 13mothers (32.5%) had moderate edema. Post test day3 revealed that 4mothers (10%) had no edema and 36mothers (90%) had mild edema. There was no significant association between the degree of physiological lower leg edema and selected demographic variables like age, education, occupation, area of living, type of family, height , BMI, obstetrical score, gestational weeks except weight. Biophysical and biochemical parameters and the risk factors of physiological lower leg edema except intake of water.

Conclusion: Physiological lower leg edema is a very common problem among antenatal mothers and they are some risk factors associated with it. Leg massage is an effective and inexpensive measure to reduce the degree of physiological lower leg edema among antenatal mothers. The study concluding that leg massage is significant in reducing the risk factors of physiological lower leg edema during pregnancy among antenatal mothers.

Key words: Leg massage, Antenatal mothers, Physiological lower leg edema

CHAPTER – I

INTRODUCTION

1.1 Background of the study

"**Pregnancy is a great adventure about to begin."**

Winnie Pooh

Pregnancy brings a new meaning to the concept of beauty. It is a period of immense joy coupled with excitement. The feeling of carrying a little soul within is magnificent. It can be a single soul or more than that. **(Ayeesha., 2016)**

Getting pregnant and growing a human from scratch is a very complicated biological process that takes a lot of resources. As a result, pregnancy can have a wide range of effects on the mother, both physically and emotionally**. (Khan., 2014)**

Maternal physiological changes in pregnancy are the adaptations during pregnancy that a person's body undergoes to accommodate the growing embryo or fetus. These physiologic changes are entirely normal, and include behavioral (brain), cardiovascular (heart and blood vessel), hematologic (blood), metabolic, renal (kidney), posture, and respiratory (breathing) changes. Increases in blood sugar, breathing, and cardiac output are all expected changes that allow a pregnant person's body to facilitate the proper growth and development of the embryo or fetus during the pregnancy. The pregnant person and the placenta also produce many other hormones that have a broad range of effects during the pregnancy. **(Martha., 2014)**

Pregnancy is presumed to be a major contributory factor in the increased incidence of varicose veins in women, which in turn lead to venous insufficiency and leg edema. **(Rebecca., 2015)**

A combination of the slight increase in the permeability of the smallest of blood vessels which allow more fluid to leak out into the tissues, the additional weight of the uterus, and the downward force of gravity, slow down the rate at which blood is pumped back to the heart from the lower half of the body. Fluid often collects in the tissues of the legs and feet of pregnant

women after the first trimester, instead of being absorbed into the blood circulation. This causes swelling or edema. **(Christina., 2013)**

Edema, the perceptible expansion of the interstitial fluid volume, results from alterations in the basic physiologic mechanisms governing fluid balance. The hydrostatic pressure within the vascular system and the colloid oncotic pressure in the interstitial fluid promote movement of fluid from the vascular to the extravascular space. Fluid is returned from the interstitial space into the vascular system at the venous end of the capillary and by way of the lymphatic system. Intravascular oncotic pressure which is facilitated by plasma proteins assists in the movement of fluid back into the vessels. **(Dianne., 2013)**

Edema occurs when body fluids increase to nurture both mother and her baby and accumulate in the tissues as a result of increased blood flow and pressure of the growing uterus on the pelvic veins and the vena cava which are the large vein on the right side of the body that returns blood from the lower limbs to the heart. This causes the mother to experience this increase in swelling particularly swollen ankles and feet. At times there may be more swelling in the feet if the weight gain of the mother has been on the faster side**. (Penny., 2017)**

Edema can be caused by a problem with the circulatory system, the lymphatic system or the kidneys. It is not always a sign of a heart or circulation problem. There can be an experience of swelling due to fluid buildup from being overweight, being inactive, after sitting or standing for a long time, or wearing tight stockings. It can also be caused by inflammation in leg tissues. Inflammation may be a normal response to injury or disease, or it may be due to rheumatoid arthritis or another inflammatory disorder. There will be a feeling of pain with inflammation**. (Kelly., 2016)**

Lower leg edema may be experienced at any point during pregnancy, but it tends to be noticed around the fifth month and can increase while the mother is in the third trimester. **(Simpkin., 2015)**

A descriptive survey was conducted to determine the perceptions , prevalence and prognosis of leg edema during pregnancy among 1000 consecutive pregnant Nigerian women under the age group 17-45 years. The result concluded that the overall prevalence rate of leg edema during pregnancy was 8.5%. The earliest gestational age at which it first appeared during

pregnancy was 24 weeks, and in 100% of cases ,the lower leg edema disappeared within one week of delivery. Anemia, malnutrition, excessive body water, kidney diseases, liver diseases and hypertension/preeclampsia were the presumed causes of leg edema during pregnancy. 73% of those who have had the condition had sought treatment for it outside the hospital**. (Peter O N kwo., 2014)**

Physiological lower leg edema occurs where fluid accumulates in the feet and lower legs mostly in late pregnancy when there is a difference in the intravascular fluid volume and extravascular fluid volume. Physiological lower leg edema can be secondary to the increased venous congestion in the legs caused by pressure exerted mechanically by the uterus onto the inferior venacava and iliac veins. **(Reynolds.,2013)**

Physiological lower leg edema tends to reduce as soon as the baby is being delivered. Treatments of leg edema comprise mostly symptom reduction rather than cure and use of pharmacological and non-pharmacological approaches like foot elevation, wearing compression stockings, massage therapy etc. Massage works by directing pressure to the skin and muscle areas affected by edema. The lymphatic system is activated during the process and the fluid drains away naturally**.(Nasser., 2016)**

Leg massage has been found to decrease the level of physiological lower leg edema. Leg massage is manipulating the superficial and deeper layers of muscle and connective tissues of the limbs by massaging top of the feet, toe, lower leg and rotation of ankle over 20minutes. Leg massaging stimulates lymphatic circulation and decreases swelling. Massaging the feet from toes to calf and exercising gentle pressure with the finger pads may help to shift water out of the tissues. **(S. Rajeshwari., 2013)**

1.2 NEED FOR THE STUDY

During pregnancy a woman's body undergo many changes due to the effect of hormones. These changes can sometimes be uncomfortable, but most of the time they are normal and enable her to nourish and protect the fetus, prepare her body for labour, and develop her breasts for the production of milk. **(Gerry.,2015)**

The swollen ankles are a normal, though frustrating, for many expectant women. During pregnancy, the extra fluid in the body and the pressure from the growing uterus can cause swelling or edema in the ankles and feet. The swelling tends to get worse as a woman's due date nears, particularly near the end of the day and during hotter weather. For annoying swollen ankles, simple steps like avoid standing for long periods, stretching often when sitting for long periods, lying on left side when sleeping, wearing maternity support stockings helps in the reduction of edema.**(Schroth., et al . 2015)**

Physiological lower leg edema is found in about 80% of all pregnancies, occurring in late pregnancy. It occurs as a result of the pressure of the gravid uterus, which impedes venous return; prostaglandin-induced vascular relaxation; and reduced plasma colloid osmotic pressure. Dependent physiological lower leg edema (water retention in the interstitial space of the lower limbs) is a frequent and unpleasant accompaniment to pregnancy, causing discomfort, a feeling of heaviness, night cramps and painful parasthesia**. (Ayden., 2014)**

In recent years, there has been an increased acceptance of the use of complementary therapies within the healthcare system. The use of non-pharmacological interventions to complement modern technological medicine is proving popular among nurses and midwives in clinical practice. Leg massage is an example of an intervention that can be used for specific conditions such as leg and foot edema as it moves extravascular fluid without disturbing intravascular fluid.**(Tuna N., 2015)**

Prenatal massage has been used for centuries to reduce stress, improve overall health, and relieve muscle tension. Pregnant women have often received ambivalent responses from the health community, regarding the purpose and safety of massage during pregnancy. Studies have proved that prenatal massage therapy can be a very instrumental tool in women’s prenatal care and should be given careful consideration. It is always best find a therapist who is certified in prenatal massage.**(Wang M.Y., 2013)**

Leg massage is a complementary therapy, which is safe, convenient and simple to perform. Several studies were done on foot and leg massage in reducing edema, especially the physiological edema during the third trimester of pregnancy. **(Kaur., 2014)**

Leg massage therapy can also bring relief in physiological lower leg edema as a part of treatment. Several studies were done on foot and lower leg massage in reducing lower leg edema physiologically, reported antenatal mothers experienced no pain and better grip strength, they also had less anxiety, sleep problems. **(Yemane fessehaye., 2014)**

There are many benefits of massage therapy, such as increasing blood circulation, reducing swelling, relaxing muscles, and relieving muscle spasms. Massage therapy focuses on the specific parts of the body where the swelling occurs, such as feet, ankles, or legs. It helps you experience a healthier lifestyle free from discomfort and pain associated with swelling. Studies indicate that massage therapy performed during pregnancy may reduce symptoms of depression, ease muscle aches and joint pains, and improve labor outcomes and newborn health.**(Leach M., 2013)**

This motivated the investigator to conduct a study on leg massage in reducing degree of physiological lower leg edema among antenatal mothers.

1.3 Statement of the problem

A Study to evaluate the effectiveness of leg massage on physiological lower leg edema among antenatal mothers admitted at selected hospital , Coimbatore.

1.4 Objectives

- To identify the risk factors of physiological lower leg edema among antenatal mothers.
- To evaluate the effectiveness of leg massage on physiological lower leg edema among antenatal mothers.
- To associate the pre test degree of physiological lower leg edema with selected demographic variables and risk factors among antenatal mothers.

1.5 Assumption

- Antenatal mothers may have physiological lower leg edema due to certain risk factors.
- Leg massage may have some effect on physiological lower leg edema among antenatal mothers.

1.6 Hypotheses

- **H_1:** There will be significant difference in the pre-test and post-test degree of physiological lower leg edema among antenatal mothers.
- **H_2:** There will be significant association between the degree of physiological lower leg edema and selected demographic variables and risk factors among antenatal mothers.

1.7 Delimitations

The study is delimited to antenatal mothers of third trimester with physiological lower leg edema

1.8 Operational definitions

- **Effectiveness:** It refers to the outcome of leg massage on physiological lower leg edema among antenatal mothers.
- **Leg massage:** Massaging in circular motion the foot and lower leg to reduce physiological lower leg edema among antenatal mothers from 3rd trimester.
- **Physiological lower leg edema**: Fluid collection in the lower leg during the third trimester due to increased retention of fluid in the interstitium. Also the enlarging uterus causes mechanical obstruction to the IVC and pelvic veins causing reduced venous return.
- **Antenatal mother**: All pregnant mothers in the 3rd trimester admitted in the antenatal ward in PSG Hospitals.

1.9 Projected outcome

There may be a reduction in the degree of physiological lower leg edema during antenatal period after giving massage to the antenatal mothers.

1.10 Conceptual frame work :

Conceptualization is the process of forming ideas, designs and plans. A conceptual framework deals with the concepts assembled together by virtue of relevance to the research problem, which provides a certain frame of reference for clinical practice, research and education.

The conceptual framework of the present study is based on the Modified Wiedenbach's helping art of clinical nursing theory (Fawcett, 1997). This study was based on the concept that leg massage helps to reduce degree of physiological lower leg edema among antenatal mothers of third trimester. The Modified Wiedenbach's helping art of clinical nursing theory as a base for developing the conceptual framework. Ernestine Wiedenbach proposed a prescriptive theory for nursing, which is described as conceiving of a decide solution and the ways to attain it. It directs action towards an explicit goal. This theory has three factors.

1. Central purpose
2. Prescription
3. Realities

Central purpose: it refers to what the nurse wants to accomplish. It is the overall goal towards which a nurse strives. In this study the main central purpose is to assess the effectiveness of leg massage in reduction of degree of physiological lower leg edema among antenatal mothers.

Realities: it refers to the physical, physiological, emotional and spiritual factors that involves in nursing actions. In this theory there are four realities. They are 5 realities which has been identified by Wiedenbach are as follows:

Frame work: It refers to the place in which it is practiced. Here it refers to the study was conducted at the antenatal ward, PSG Hospitals.

Agent: One who directs all action towards the goal and has capacities, capabilities, commitment and competence to provide care. In this study, agent is the researcher who directs all the action towards the goal.

Recipient: One who is vulnerable and dependent and receive all attention. Here are the antenatal mothers of third trimester those who are having physiological lower leg edema are the recipient of the leg massage.

Goals: It refers to the desired outcome of the action. Reduction in the level of physiological lower leg edema was considered as the goal of the study.

Means: This refers to the activities or devices used to achieve the goal. In this study it refers to application of leg massage to the antenatal mothers of third trimester having physiological lower leg edema.

The conceptual framework of this study is based on Modified Wiedenbach's helping art of clinical nursing theory. According to her nursing practice it consists of this setup which include:

1. Identifying need for help
2. Ministering the needed help
3. Validating that the need was met

Identifying need for help: It refers to the viewing the individual's unique experiences and perceptions. In this study the antenatal mothers with physiological lower leg edema is assessed by the demographic variables and Modified Erwin edema tool.

Ministering the needed help: This step involves provision of required help for the identified need. The leg massage is given 20 minutes per day till discharge to the samples.

Validation: It refers to reduction in the degree of physiological lower leg edema through the identification of need and implementation of action. Here it is the post assessment of degree of physiological lower leg edema using modified Erwin edema tool after administration of leg massage till discharge.

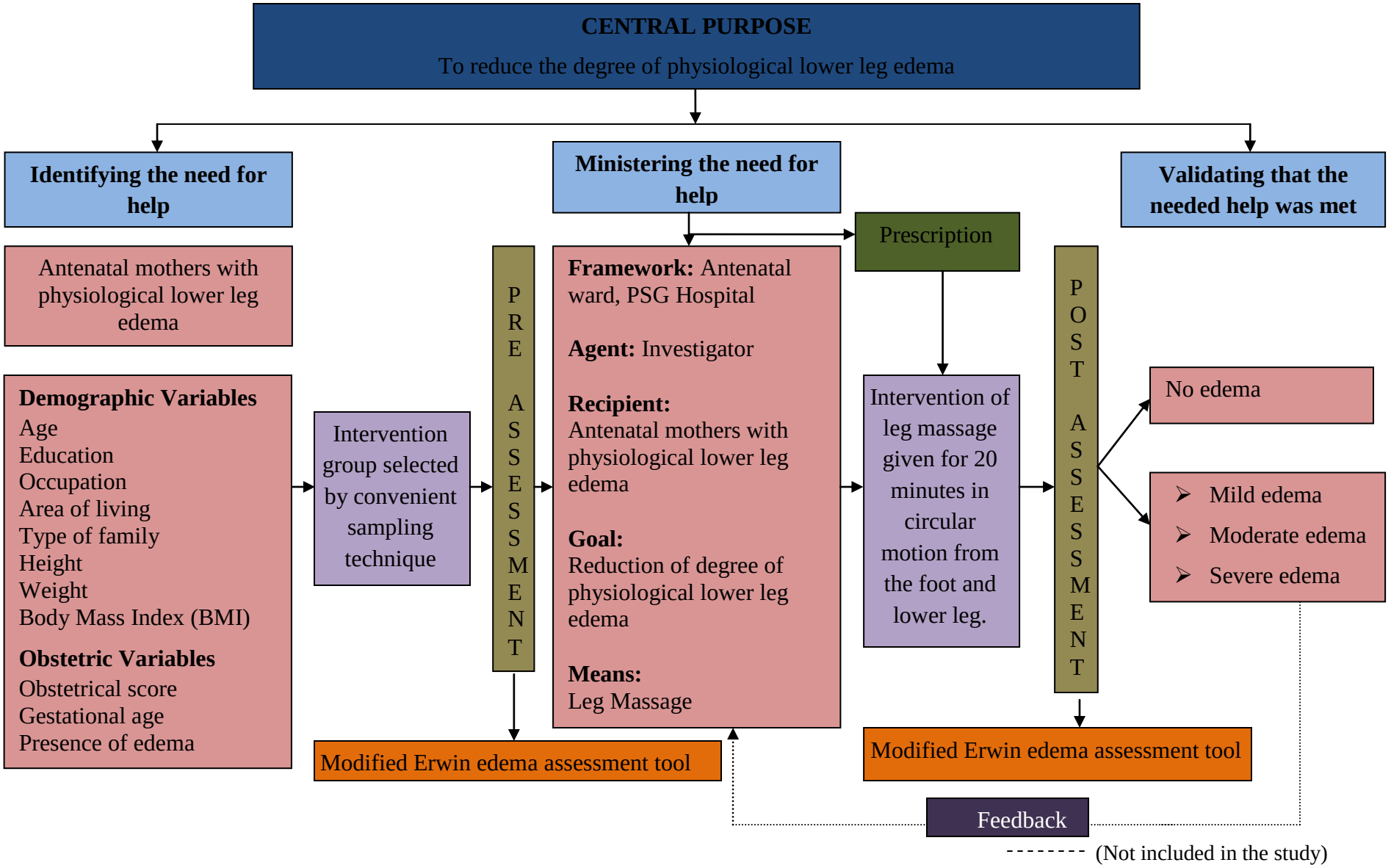

Figure 1.1 Modified Wiedenbach's helping art of clinical nursing theory to evaluate the effectiveness of leg massage on physiological lower leg edema among antenatal mothers

CHAPTER-II

REVIEW OF LITERATURE

A literature review is the critical analysis of segment of published research studies, reviews of literature, and theoretical articles. A literature review is an evaluation report of studies found in literatures related to selected areas. The review should describe, summarize, evaluate and clarify the literature. It should give a theoretical basis for the research and help to determine the nature of research. A literature review goes beyond the search for information and includes the identification and articulation of relationships between the literatures and field of research.

This chapter consists of literature and research studies related to:

2.1 Studies related to risk factors of physiological lower leg edema

2.2 Studies related to the effect of leg massage on physiological lower leg edema

2.3 Studies related to alternative and complimentary care

2.1 Studies related to risk factors of physiological lower leg edema

A descriptive study was conducted to assess risk factors and to analyze methods applied in the prevention and treatment of lower limb edema in pregnant women with a particular focus on compression therapy and exercise among 54 women. Women were assigned in 2 groups either to a group with swellings of lower limbs during pregnancy, located mostly in the region of feet and lower legs and to a group without edema. The analysis has led to a conclusion that there is a link between the occurrence of edema during pregnancy on the one hand and the pre gravidity episodes of venous conditions (vascular insufficiency and thrombosis, $p<0.05$) and the lack of physical exercise during pregnancy ($p=0.01$) on the other hand. Only 33% of the analyzed women applied compression therapy during pregnancy; a half of them continued to apply compression during the postpartum period. Compression therapy in combination with proper physical exercises appears to be an effective means to prevent and treat venous thrombosis and lower limb edema in pregnant women**. (Ochalek K, et al., 2017).**

A cross sectional assessment study was conducted to analyze the stress scores among the outpatients of a tertiary care hospital who come for regular antenatal check up. The women at the gestation weeks between 28 to 34 weeks agreed to participate in the study. They were interviewed to assess the perceived stress score. Among the total patients 57.7% were primigravida and the mean score on perceived stress scale was 13.5±5.02. The majority of the group (102; 65.4%) scored higher than the mean value of total score on the perceived stress scale. Unplanned pregnancy and husband's employment status were associated with high levels of perceived stress in multivariate analysis in this set of women**. (Anuja Abraham, 2015)**

A descriptive survey was conducted to find out the prevalence of varicose vein and edema in nurses estimated to be 16.18%. The factors significantly associated with venous reflux were increasing age and prolonged working hours (≥ 4 hours) in a standing position, even after risk adjustment for socio demographic factors. This study is significant in that an objective diagnosis of edema preceded the analysis of the risk factors for varicose veins incidence, thus verifying objectively that edema is associated with occupations requiring prolonged hours of working in a standing position**. (Gaffney., 2014)**

A study was conducted to analyze the duration of standing according to work among 204 hairdressers with a self reported questionnaire. The duration of standing was reported to be between 82% and 99% of total work time. Back pain was the most reported musculoskeletal disorder followed physiological lower leg edema due to long time standing work. **(Best et al., 2014)**

A case control study was conducted to determine the risk of back pain and physiological edema in antenatal mothers which varies in relation of style of footwear worn. Flat sandals and shoes were the styles of footwear associated with low risk of back pain and physiological lower leg edema. Going barefoot or in stocking feet was associated with sharply increased risk, even after controlling for measures of health status. Relative to flat sandals/shoes, other footwear was associated with a 1.3-fold increase in the risk of both back pain and lower leg edema varying somewhat by style.**(Cronin., 2014)**

A population-based , case-control study on caffeine intake and the risk of physiological lower leg edema in pregnancy was conducted among 562 antenatal mothers after 30 weeks of gestation (the case patients) and 953 mothers who did not have edema and were matched to the case patients according to the week of gestation (controls). Information on the ingestion of caffeine was obtained from in-person interviews. Among the samples more degree of lower leg edema occurred in women who ingested atleast 100mg of caffeine per day than in mothers who ingested less than 100mg of caffeine per day , with the increase in risk related to the amount ingested When the analyses were stratified according to the results of karyotyping, the ingestion of moderate or high levels of caffeine was found to be associated with an excess risk of moderate edema. This concluded that caffeine may increase the risk of mild leg edema among antenatal mothers. **(William., 2014)**

A study was conducted among sixteen women traffic control agents were assessed by water displacement volumetry and the results were analyzed in two groups, depending on working posture. Those who worked standing up for more than 4 hours were allocated to the SU group and those who worked sitting down for more than 4 hours were allocated to the SD group. Each worker was assessed before and after their working shift for three consecutive days. Data were analyzed using ANOVA and the test of equality of two proportions. 0The assessment showed that members of both groups had lower leg edema of the lower extremities ($p \leq 0.001$). **(Anna Paula., 2013).**

2.2 Studies related to the effect of leg massage on physiological lower leg edema

A quasi experimental study was conducted to determine the effect of leg massage on physiological lower leg edema level among antenatal mothers. The study was conducted at OBG Department in Menoufia University Hospital. A purposive sample of sixty four mothers who were under third trimester was assigned alternatively & randomly into two equal groups. Thirty two patients for each group (study &control). An interviewing questionnaire to assess socio demographic data. The results showed that there were statistically significant reduction in the degree of physiological lower leg edema among study group rather than control group after leg massage. There was no significant relation between edema degree and gender, education &

marital status. So leg massage has a positive effect on reducing degree of physiological lower leg edema among antenatal mothers**. (Amal El. Shehata, et al., 2016).**

An experimental study was conducted to test the impact of leg massage on the level of physiological lower leg edema among antenatal mothers. Sample comprised 30 antenatal mothers selected by purposive sampling method. Pre-assessment edema degree, heart rate, and blood pressure were recorded. Leg massage with low stroke manipulations was applied on each leg of the subject for 15 minutes. The result showed that there was a significant difference between pre- and post-leg massage lower leg edema score, heart rate, and blood pressure ($P<0.05$). The study concluded that leg massage is an effective non pharmacologic measure in reducing physiological lower leg edema. **(Muller, 2016).**

A cross sectional study was conducted 1000 consecutive eligible pregnant Igbo women who presented at the antenatal clinic of the Park Lane Specialist Hospital Enugu over a 10-month period. The data were collated and analyzed with the computer statistical software SPSS version 15 for descriptive and inferential statistics. Level of significance was set at $p<0.05$ (95% confidence interval). The overall prevalence of leg oedema during pregnancy was 8.5%.All the women (100%) however believed that leg oedema during pregnancy is abnormal and requires treatment. All the 85 respondents (100%) of those who had leg oedema were offered only reassurance without drug in the hospital. However, 62(73%) of those who had leg oedema admitted receiving some forms of drug treatment. **(Ohang., 2015)**

A randomised controlled study was conducted to evaluate the effects of leg massage on physiological lower leg edema among sixty-two Taiwan mothers who are under third trimester of pregnancy. Mothers were given 20 minutes of leg massage. Mothers in the control group received usual edema management. Results indicated that less edema ($P<0.05$) over time were reported by the intervention group compared with the control group. The study concluded that leg massage is an effective intervention in reducing physiological lower leg edema among antenatal mothers. **(Piner, 2015).**

A non-randomized clinical trial was conducted to evaluate of the effect of leg massage and foot elevation on physiological lower leg edema during pregnancy among 180 healthy pregnant women assigned to three groups. In the first group, massage was performed for 20

minutes. In the second group, foot elevation was performed for 20 minutes. The third was the control group where no manipulation was done. The intervention was performed during 5 days, and lower leg edema measured. After the intervention there is a significant difference between the 3 groups in terms of the mean rate of change of the circumferences ($P<0.001$). The results indicated that the greater effect of massage compared with foot environment was measured in feet ($P<0.001$). The results of this study showed that massage therapy is effective in reducing physiological lower leg edema during pregnancy. Therefore the leg massage can be performed by midwives and as a useful intervention.**(Fatemeh., 2015)**

A quasi experimental study was conducted to determine the effectiveness of leg massage in reducing physiological lower leg edema in mothers admitted in antenatal Ward, CMC Vellore. A sample of 30 mothers was selected from the antenatal Ward where mothers were in their third trimester. Each mother was given 20 minutes of leg massage, pre and post-assessment of physiological lower leg edema was done using pitting edema scale. Results showed after leg massage the edema degree of 19 mothers (63.3%) were reduced from severe to moderate and for (6.6%) was reduced from moderate to mild and for 9 mothers (30%) it remained in same level. A significant difference between pre and post nursing intervention in reduction of physiological lower leg edema for 30 samples ($p<0.01$). The study concluded that the leg massage is the best nursing intervention and it can be introduce into nursing curriculum as a best method of pain reduction. **(Khalilian, 2014).**

An experimental study was conducted to determine the efficiency of leg massage on reducing physiological lower leg edema among Turkish women among 281 antenatal mothers using random sampling method. The study found that the difference between the rating scores before and after massage ($p<0.01$) and the Rating Scale scores before and 60 minutes after the massage ($p<0.001$) was statistically meaningful. The findings indicated that the edema degree of the mothers in the intervention group were significantly different than the control group. The study concluded that leg massages were useful as an effective nursing intervention in controlling physiological lower leg edema. **(Wang, 2013).**

A study was conducted to assess the effect of leg massage for decreasing physiological lower leg edema in late pregnancy. Eighty pregnant women were randomly divided into two groups and the study group had a 20 min leg massage daily for 5 days whereas the control group

did not receive any intervention beyond standard prenatal care. The research was conducted between March and August 2012 in Manisa Province Health Ministry Central Primary Health Care Clinic 1, in Manisa, Western Turkey. Compared with the control group, women in the experimental group had a significantly smaller lower leg circumference (right and left, ankle, instep and metatarsal–phalanges joint) after 5 days of massage. The results obtained from our research show that leg massage was found to have a positive effect on decreasing normal physiological lower leg edema in late pregnancy**. (Coban A., 2013).**

A study was being conducted by the Turkish researchers by randomly selecting 80 pregnant women into 2 groups in which a study group that received a 20-minute foot massage daily for five days , and a control group that did not receive any intervention. Compared to control group, women in experimental group had a significantly smaller lower leg circumference (right and left, ankle, instep and metatarsal phalanges joint)after five days of massage. The results obtained from the research shows that foot massage was found to have a positive effect on decreasing normal physiological lower leg edema**. (International Journal of Nursing Practice., 2012).**

2.3 Studies related to alternative and complimentary care

The use of reflexology as a complimentary treatment for edema. Reflexology involves the application of pressure to reflex areas of the hands or feet to produce specific effects in other parts of the body. The thumb and finger technique was used. The researcher divided the body into 10 longitudinal zones (5 on each side of the body) terminating in the toes and fingers and suggested that a direct link existed between these areas and the organs of the body within a given zone. Reflexology is a complimentary natural healing therapy that can help the body, mind and soul on many levels and can definitely help in reducing swelling in the feet as the reflexes of the feet receive acupressure treatment **.(Ottawa.,2017)**

It is found that there is effectiveness of manual lymph drainage over leg edema. Manual Lymph Drainage (MLD) massage is often helpful in reducing edema because it stimulates blood flow, fluid movement and lymphatic system function (detoxifying our bodies). Manual lymph drainage massage strokes are often made in upward motions toward the heart to encourage the lymph movement**. (Yumiko., 2017)**

Another complimentary therapy can be foot elevation as a routine care for physiological lower leg edema. Foot elevation is done for women experiencing swelling of the legs and feet without any reason. Her legs should be elevated above the level of her heart to keep the swelling down using gravity. For swollen legs and feet caused by pregnancy, pregnant women should also elevate their legs and avoid lying on their back in order to help improve the blood flow and reduce the swelling. The subcutaneous extravascular fluid in the legs and feet should then move toward the pelvis. **(Harvard Health Publication., 2017)**

A quasi experimental, comparative study was conducted in the clinics of OBG Department in Mansoura university. The sampling technique was purposive sampling with samples of 80 pregnant women who were chosen and divided into two equal groups for sitting upright in a chair with legs elevated or immersed their legs in water for 20 minutes. Changes in leg volume of edema were assessed by pitting edema techniques immediately pre- and post-intervention" immediately and after two weeks". Results of this study revealed that highly significant variations between pre- and post-interventions for both groups and equal, non significant differences between both interventions (leg elevation and water immersion). Conclusion was leg elevation and water immersion are necessary to alleviate edema in lower extremities during pregnancy**. (Dr.Reda Hemida, et al., 2016).**

The pressure of an elastic stocking on the swelling skin is less than that of a bandage. At rest, stockings generate an almost constant pressure known as the resting pressure, and with movement, such as when walking, the stockings generate variations in pressure. It was reported that the in patients with venous leg edema, a compression pressure of around 20 mmHg is exerted by a stocking led to a reduction in edema comparable to that achieved by an inelastic bandage applied with a pressure of around 60 mmHg when both systems were worn day and night for 1 week. External compression increasing the tissue pressure may reduce the capillary filtration. A stocking with a very low pressure may therefore be sufficient to obtain an effect of reducing the capillary filtration. **(Mosti.G., 2013)**

Summary:

The researcher has reviewed the theoretical and empirical literatures related to risk factors of physiological lower leg edema, effect of leg massage on physiological lower leg edema and alternative and complimentary care which helps in the identification of risk factors and the effective measures which can be taken to reduce physiological lower leg edema.

CHAPTER – III

MATERIALS AND METHODS

Methodology of research indicates the general pattern of organizing the procedure for gathering valid and reliable data for the purpose of investigation. Methodology of the study constitutes research design, variable setting of the study population, sampling technique, sampling criteria description of tool, data collection procedure and methods of analysis based on statement and objectives of the study. This chapter gives a brief description of method adopted by the investigator for the study.

The present study is aimed to evaluate the effectiveness of leg massage on physiological lower leg edema among antenatal mothers admitted at selected hospitals, Coimbatore.

3.1 Research approach and design

Pre experimental one group pre test – post test design was used in this study. This design measures the effect on the experimental group, based on their state before the beginning of the experiment (pretest) and the difference achieved at the end of the experiment (posttest). There is no control group in this design.

O_1-Observation (pre-test)

X-Intervention (Leg massage)

O_2-Observation (post test)

The design is one group pre-test post-test design which comes under pre-experimental design.

3.2 Variables of the study:

3.2.1 Independent variable:

The independent variable of the study is leg massage.

3.2.2 Dependent variable:

The dependent variable is physiological lower leg edema.

3.3 Setting of the study:

PSG Hospital is a multi speciality hospital and research centre with bed strength of 1315 which caters multi lingual patients from various parts of the country. The PSG Hospitals has an outpatient facility whereby around 1000 patients take medical advice every day. This is the first teaching hospital in Tamilnadu and the third teaching hospital in India to get certified by National Accredited Board for Hospitals and Health Care Providers (NABH). The study was conducted among antenatal mothers in third trimester admitted in the antenatal ward which has a bed strength of 32 beds.

3.4 Population and sampling:

The target population composed of antenatal mothers of third trimester with physiological lower leg edema admitted at PSG Hospitals, Coimbatore

3.4.1 Sampling technique and sample size:

The samples for this study were the antenatal mothers with physiological lower leg edema who were selected on the basis of non probability convenient sampling technique who met the inclusion criteria. Total sample size is 40 which is calculated by power analysis method.

Sample size and calculation:

Power analysis method

$$n = \frac{Z^2 \times N \times SD_p^2}{(N-1)\tilde{e}^2 + Z^2 \times SD_p^2}$$

$$n = \frac{(.96)^2 \times 132 \times (.5)^2}{(32-1) \times 1^2 + (.96)^2 \times (.5)^2}$$

$$= \frac{6209.2}{178.82} = 34.7$$

$$n = 34$$

Sample size is 40

N = size of population

n = size of sample

e = acceptable error

SD_p = standard deviation of a population

Z = standard variation at a given confidence level

3.4.2 Sampling Criteria:

Inclusion criteria:

Antenatal mothers

- with physiological lower leg edema
- who are willing for leg massage.
- under the age group 20-37years.
- Third trimester of pregnancy.

Exclusion criteria:

- Antenatal mothers who are known case of any medical illness like renal disorders, anemia, varicosities, and hypertensive mothers.
- Antenatal mothers who have taken barely water and jeera water as a measure to reduce edema.

3.5 INSTRUMENTS AND TOOL FOR DATA COLLECTION:

Tool consist of three sections

Section A.

- **Tool 1: Demographic data** (age, education, occupation, type of family, area of living, height, weight and BMI).**Obstetrical profile** (obstetrical score, gestational weeks).
- **Tool 2: Biochemical and biophysical variables** (Blood pressure, sodium level, hemoglobin, blood glucose level, urine albumin).

Section B

- **Tool 3: Questionnaire** to assess the risk factors of physiological lower leg edema among antenatal mothers. The risk factors for the assessment of physiological lower leg edema are (family history, presence of lower leg edema in previous pregnancy, sitting for long time, standing for long time, wearing tight stockings, types of footwear, hours of rest taken, position during sleep, timing of severity, travelling, dietary habits, coffee consumption, intake of water, salt intake). The measures used to reduce edema (foot elevation, wearing compression tights, avoiding outdoor, applying cold compress, wearing loose cotton clothes, any others, none).

Section C

- **Tool 4: Modified Erwin edema tool** to assess the degree of physiological lower leg edema. The constituents necessary to assess the degree of physiological lower leg edema are areas of edema (lower $1/3^{rd}$ of tibia, dorsalis pedis, median malleolus, all of the above) distribution (unilateral, bilateral, none)depression (no detectable depression, 2mm depression, 4mm depression, 6mm depression, 8mm depression) rebounding time(not seen, immediate rebound, few seconds to rebound, 10-12 seconds to rebound, greater than 12 seconds to rebound) pain (absent, present) feeling of heaviness (absent, present).

SCORING AND INTERPRETATION

0	-	no edema
1-6	-	mild edema
7-11	-	moderate edema
12-16	-	severe edema

3.5.1 Validity and reliability of tool:

Validity of the tool:

Validity of the tool was determined by obtaining opinion from the experts of specialized fields in obstetric and gynecological nursing and medical department. The tool was modified based on the suggestions of the experts.

Reliability of the tool:

Reliability of the questionnaire for assessment of risk factors was done by using split half method. The reliability was 0.84. The reliability for modified Erwin edema tool was identified by using inter rater reliability method. The reliability of tool was found to be 0.92 which is reliable.

3.5.2Techniques of Data collection:

Demographic data (age in years , education , occupation , type of family , place of living , height , weight and BMI), Obstetrical variables (obstetric score , gestational weeks), biochemical and biophysical profile(blood pressure , sodium level , hemoglobin , blood glucose, urine albumin) and questionnaire was collected through interview method and retrieved from the mothers and medical records. Physiological lower leg edema among antenatal mothers were assessed using modified Erwin edema tool.

Intervention

- Place the mother in a comfortable position. Leg massage is given specifically targeting the muscles in the foot and lower leg for 20 minutes.
- Spread oil on the feet and lower leg and rub the oil from the heels to the lower leg.

- Hold the heel in one hand and start rotating the toe in a gentle motion, four times clockwise and four times anti-clockwise. Using the finger pads massage the top of the feet in a circular motion from toes to ankle.
- Perform internal rotation, external rotation and plantar flexion 3 times each respectively by holding the feet.
- Using the fingers, massage the toes completely.
- Massage with gentle stroke along the feet and leg with the finger pads towards the heart and in circular motion on the joints including patellar and popliteal surface.
- The post test degree of edema was assessed after 6 hours of intervention by using modified Erwin edema scale.

3.6 Ethical approval:

The Institutional Human Ethics Committee, PSG Institute of Medical Science and Research reviewed the proposal on its full board meeting and approved the study to conduct. The Institutional Human Ethics Committee consists of fifteen members of different areas of expertise. After getting clearance from Institutional Human Ethics Committee data collection was done.

Data collection procedure

Formal written permission was sought from the Principal, Dean and Head of the department of obstetrics and gynecology, PSG Hospitals, Peelamedu, Coimbatore. The approval for conducting the study was received from IHEC of the Institution. The data collection procedure was carried out from 01-02-2018 to 28-02-2018. The samples were selected using convenient sampling technique and the screening was done among the antenatal mothers of third trimester with physiological lower leg edema. The written consent was obtained from the all the selected antenatal mothers as there is no control group. The sample size is 40. The pre assessment was done using modified Erwin edema tool and pre test was done by using the questionnaire. The intervention of leg massage was given for 20 minutes in each leg. The post test level of edema was assessed after 6 hours of the intervention given by using Erwin edema tool.

Data collection procedure

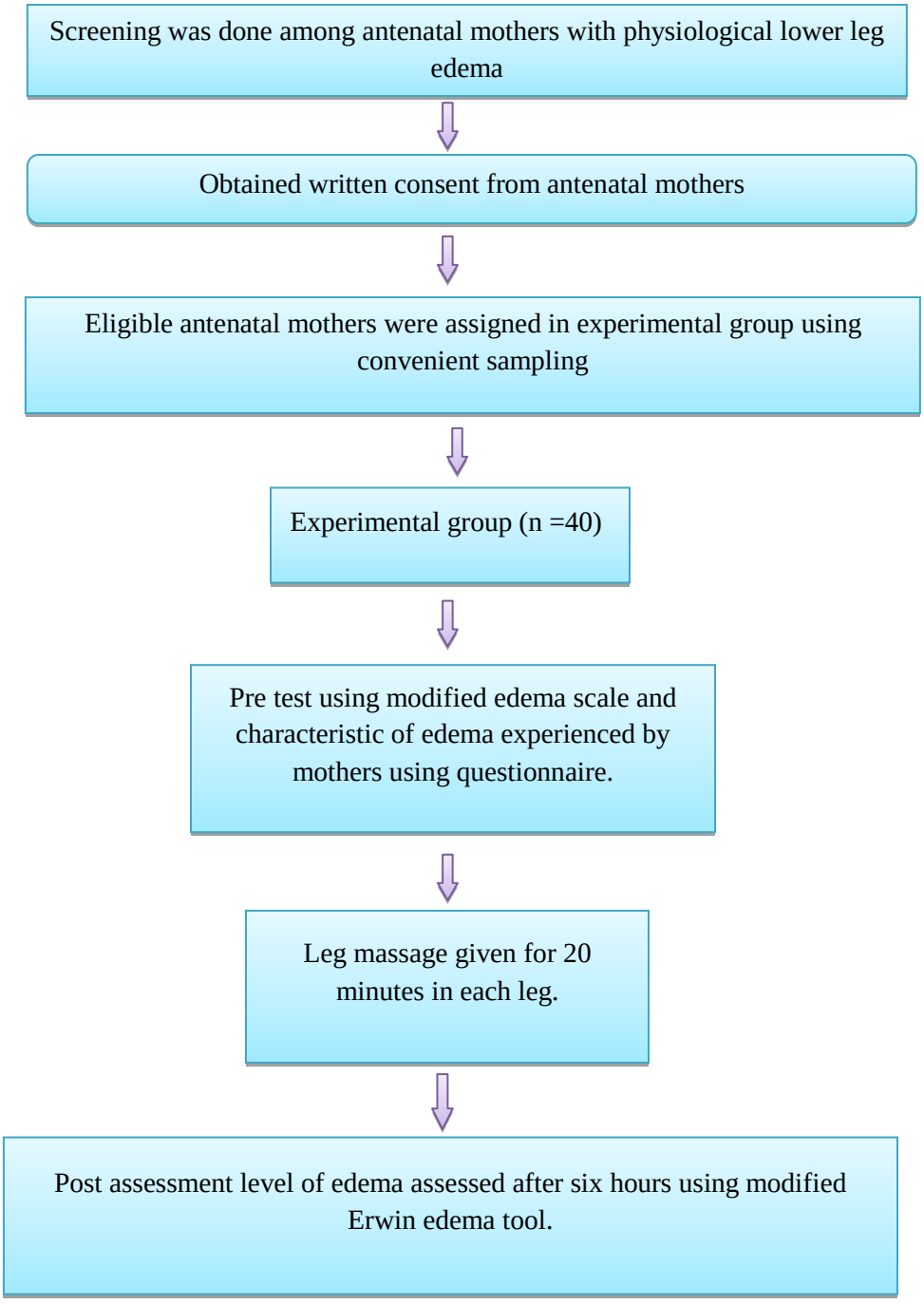

Figure 3.1 Schematic representation of data collection procedure

3.7 Report of the pilot study:

- Pilot study was a trial run done in preparation for the main study to test the reliability, practicability, appropriateness and flexibility of the study and tool.
- After obtaining permission from the authorities and ethical committee the researcher conducted pilot study with 10 samples for a period of 1 week from 30-10-2017 to 5-11-2017 in antenatal ward, PSG Hospitals.
- Based on the inclusion criteria, samples were selected by using convenient sampling technique.

3.8 Data analysis plan:

The collected data were analysed by using descriptive and inferential statistics

Descriptive statistics:

- Frequency and percentage distribution of samples to assess the demographic variables.
- Frequency distribution, mean, standard deviation will be used to describe the degree of physiological lower leg edema before and after leg massage.

Inferential statistics:

- Paired 't' test was used to find the significant differences between the pre-test and post-test degree of physiological lower leg edema among antenatal mothers.
- Chi square test was used to find out the association of pre test degree of physiological lower leg edema.

CHAPTER-IV

DATA ANALYSIS AND INTERPRETATION

Analysis is a process of organizing the data in such a way that research question can be answered. This chapter deals with the analysis and interpretation of the data collected from the antenatal mothers to assess the effectiveness of leg massage in reducing degree of physiological edema among antenatal mothers at PSG Hospital. The collected data were tabulated, organized, sections which includes:

4.1: Frequency and percentage distribution of demographic variables among the antenatal mothers with physiological lower leg edema

4.2: Frequency and percentage distribution of risk factors of physiological lower leg edema among antenatal mothers.

4.3: Frequency and percentage distribution of degree of physiological lower leg edema present among antenatal mothers.

4.4: Comparison of mean and standard deviation of degree of physiological lower leg edema between pretest and post test scores among antenatal mothers using paired ‘t’ test.

4.5: Association between pretest degrees of physiological lower leg edema with selected demographic variables and risk factors among antenatal mothers.

Section 4.1: Demographic data and obstetric variables of antenatal mothers with physiological lower leg edema

Table 4.1.1: Frequency and percentage distribution of subjects with physiological lower leg edema according to demographic variables n=40

S.NO	Demographic variables	Frequency (f)	Percentage (%)
1	**Age in years**		
	20yrs-28yrs	32	80
	29yrs-37yrs	8	20
2	**Education**		
	Primary	-	-
	Secondary	6	15
	Graduate	32	80
	Post graduate	2	5
3	**Occupation**		
	House wife	33	82.5
	Employed	7	17.5
4	**Type of family**		
	Joint family	8	20
	Nuclear family	32	80
	Extended family	-	-
5	**Place of living**		
	Urban	28	70
	Rural	12	30
6	**Height**		
	130-140	-	-
	141-150	12	30
	151-160	24	60
	161-170	4	10
7	**Weight**		
	50-60	2	5
	61-70	20	50
	71-80	15	37.5
	81 and above	3	7.5
8	**BMI**		
	18.5 and below	-	-
	18.5-24.9	1	2.5
	25 and above	39	97.5
9	**Obstetric score**		
	Primi gravid	25	62.5
	Multipara	15	37.5
10	**Gestational weeks**		
	32weeks-36weeks	18	45
	37weeks-40weeks	22	55

Table4.1 reveals that among 40 subjects, 32(80%) of the subjects are within the age group of 20yrs-26yrs and have finished their graduation, belonging to nuclear family. Most of the subjects 33(82.5%) are house wives.

More than half of the subjects 28(70%) live in urban area. More than half of the subjects 24(60%) have a height of 151-160cm, 12(25%) have a height of 141-150cm and 4(10%) is within the height of 161-170cm. 20(50%) of the subjects have a weight of 61-70kg, some of the subjects 15(37.5%) weigh in the range of 71-80kg. 2(5%) of the subjects weigh in between 50-60kg and the3(7.5%) weigh 81 and above. Majority of the subjects 39(97.5%) have a BMI of 25 and above and only one (2.5%) subject has BMI of 18.5-24.9.

More than half of the subjects 25(62.5%) are primi gravida and the 15(37.5%) are multipara. Most of the subjects 22(55%) fall under the gestational group of 37weeks – 40weeks and 18(45%) fall under 32weeks – 36weeks.

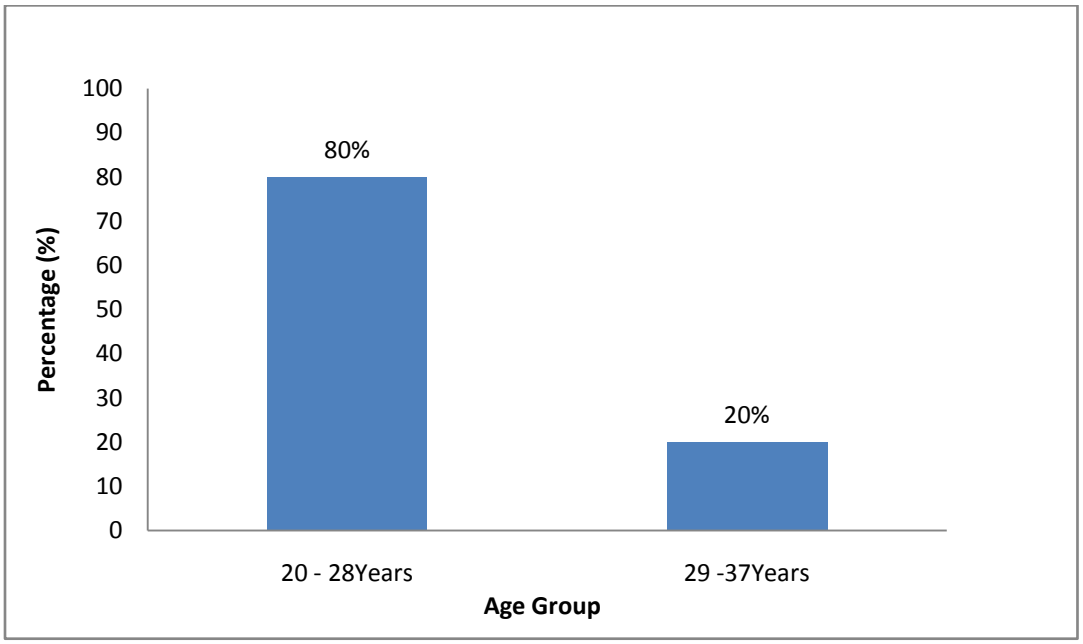

Fig 4.1.1 Clustered Column diagram showing the distribution of subjects by age in years

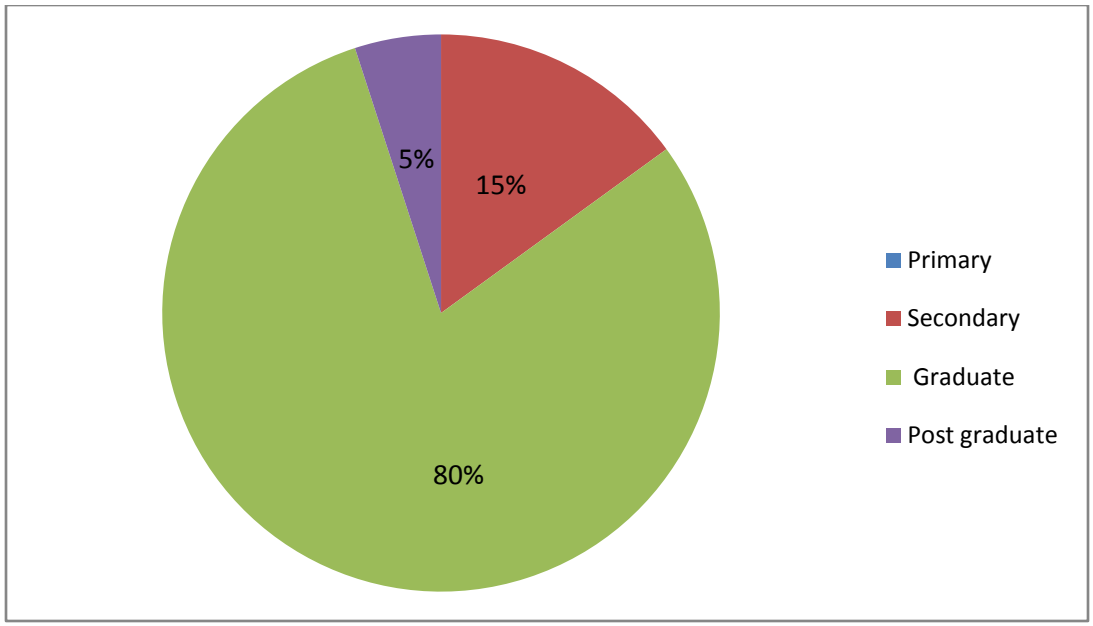

Fig 4.1.2 Pie diagram showing the distribution of subjects on the basis of education

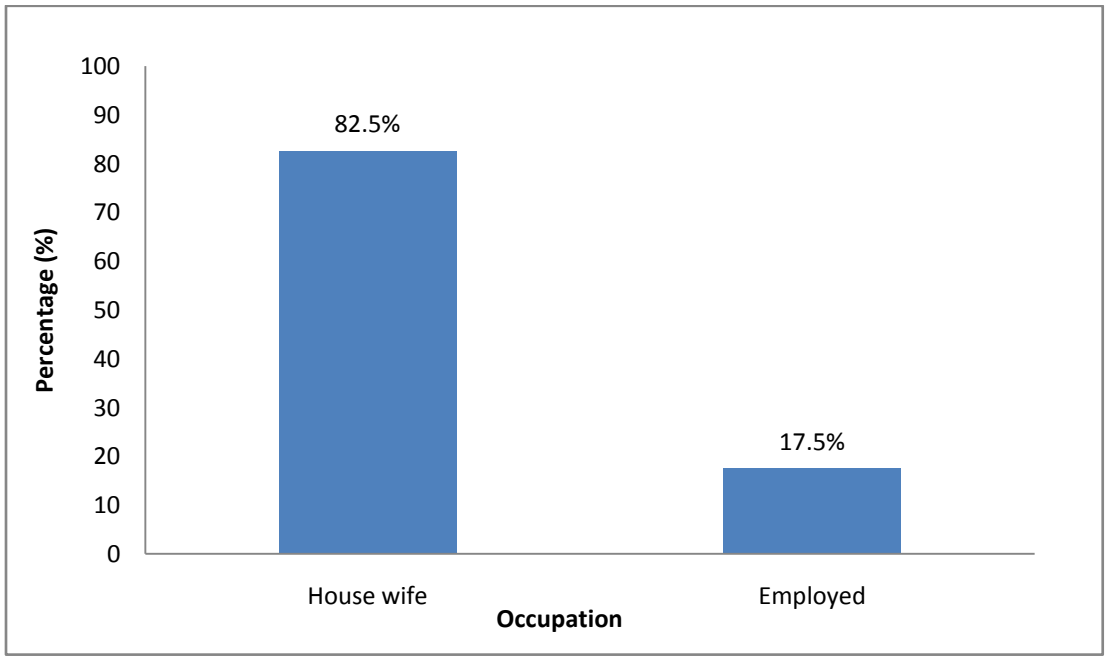

Fig 4.1.3 Clustered Column diagram showing the distribution of subjects on the basis of occupation

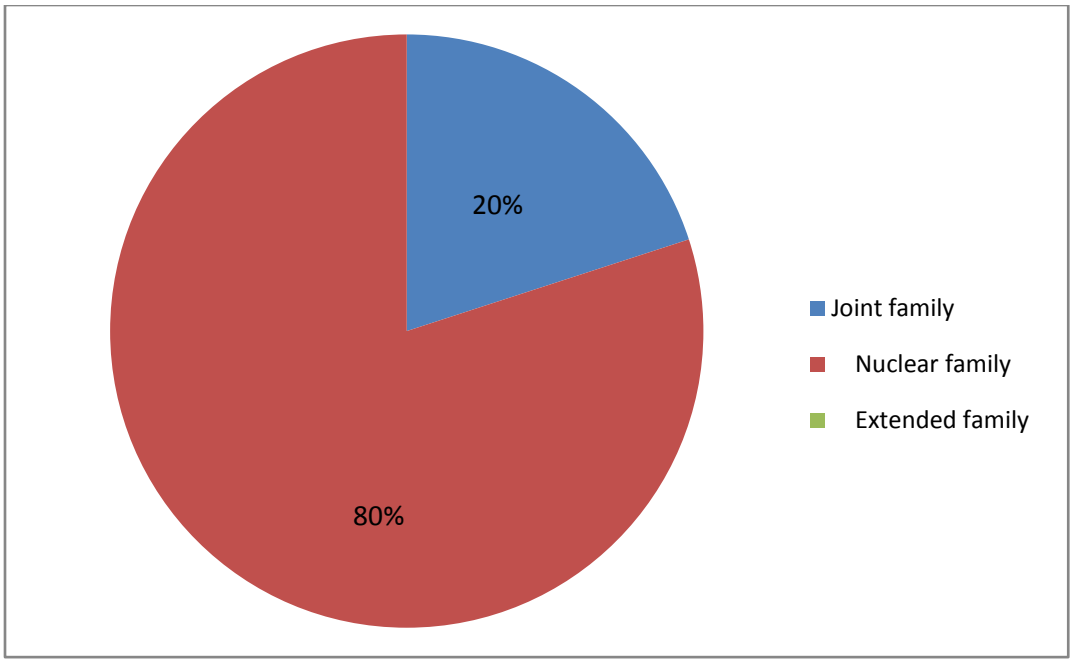

Fig 4.1.4 Pie diagram showing the distribution of subjects on the basis of type of family

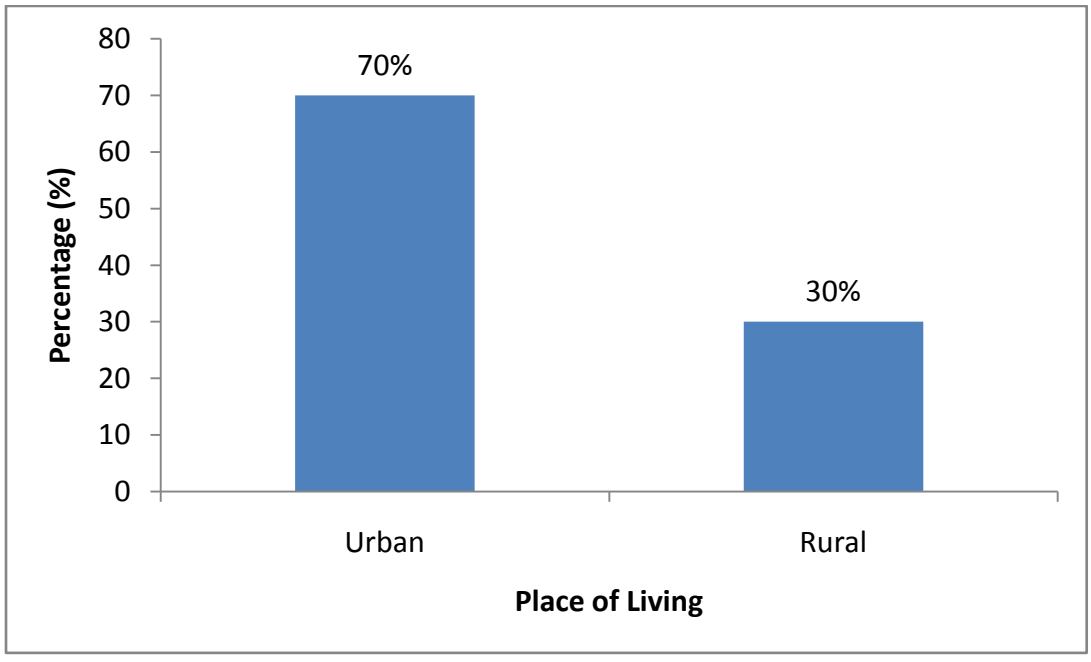

Fig 4.1.5 Clustered Column diagram showing the distribution of subjects on the basis of place of living

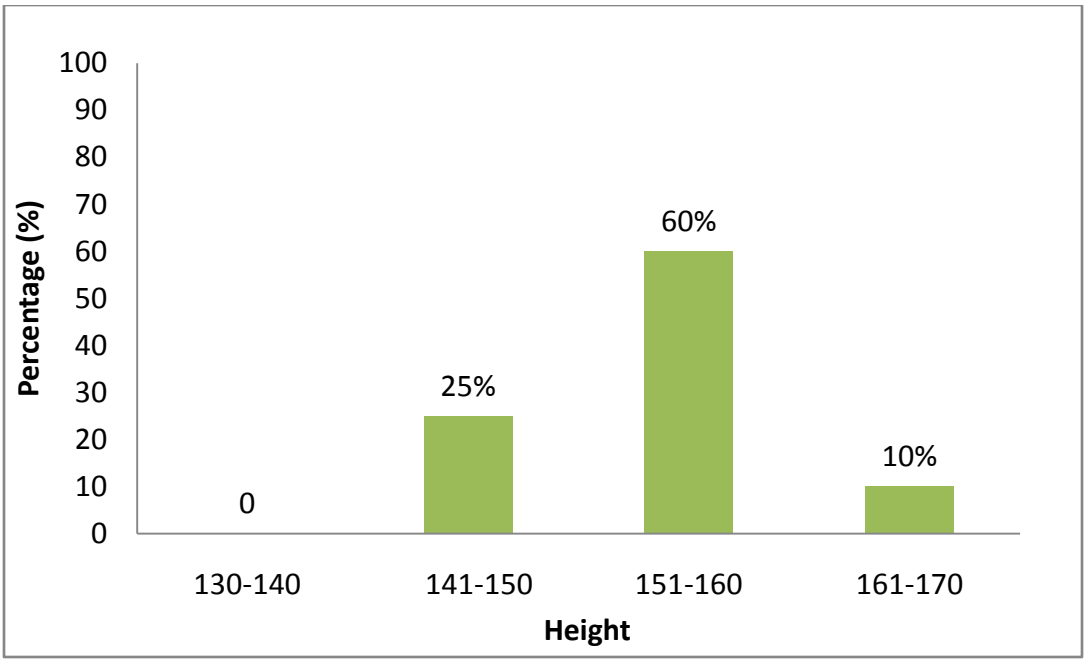

Fig 4.1.6 Clustered Column diagram showing the height variation among subjects with physiological lower leg edema

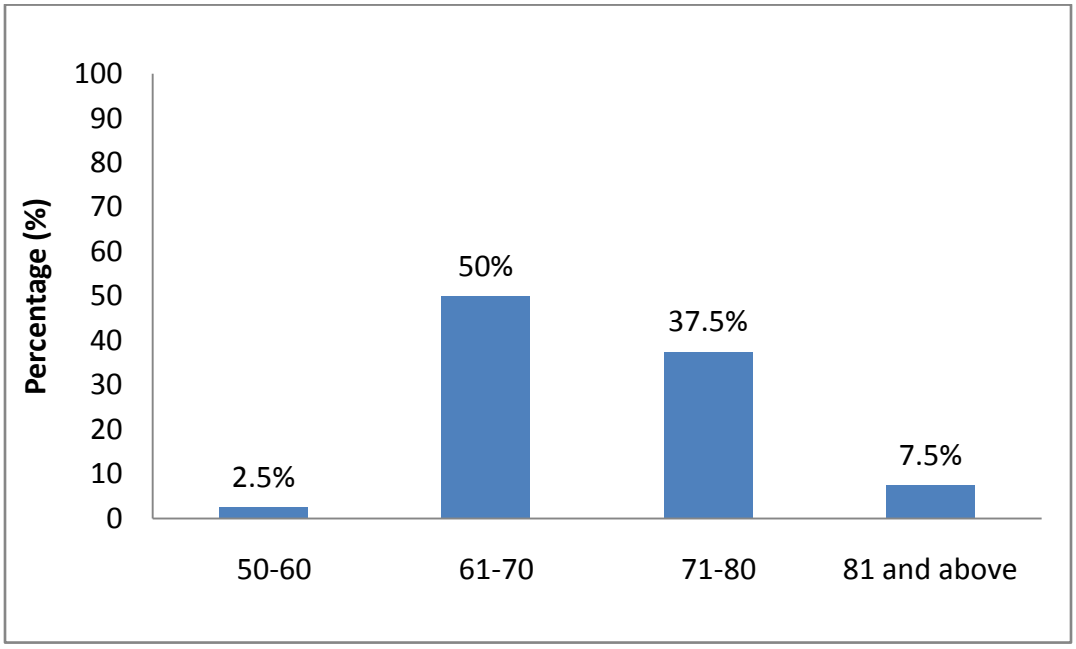

Fig4.1.7 Clustered Column diagram showing the weight variation among subjects with physiological lower leg edema

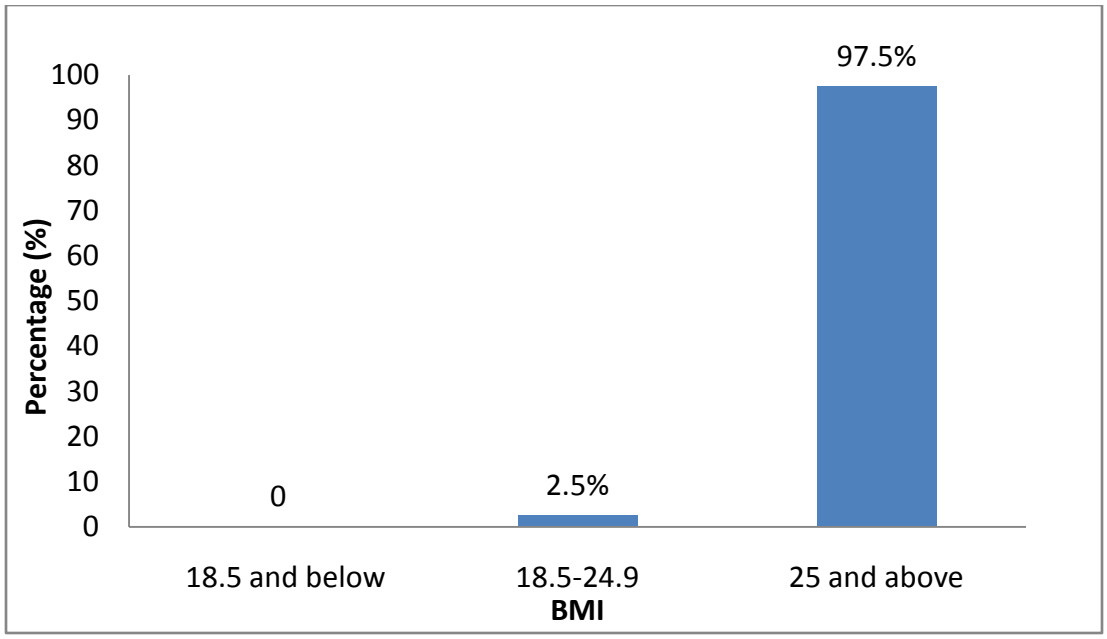

Fig 4.1.8 Clustered Column diagram showing the BMI variation among the subjects with physiological lower leg edema

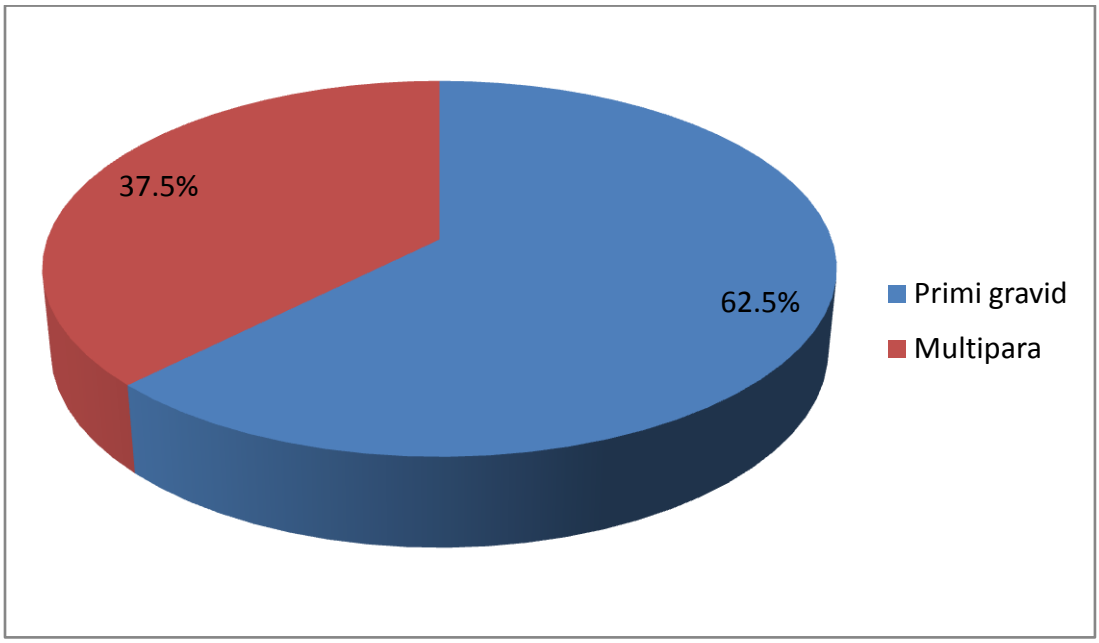

Fig 4.1.9 Pie diagram showing the obstetric score of the subjects with physiological lower leg edema

Section 4.2: Identification of risk factors of physiological lower leg edema

Table 4.2.1: Frequency and percentage distribution of risk factors of physiological lower leg edema **n=40**

S.No	Risk factors	Frequency (f)	Percentage (%)
1	Family history		
	Diabetes mellitus	9	22.5
	Hypertension	-	-
	Cardiac diseases	-	-
	None	31	77.5
2	Lower leg edema in previous pregnancy		
	Yes	11	27.5
	No	29	72.5
3	Sitting for long time(4 hrs)		
	Yes	4	10
	No	36	90
4	Standing for long time (4hrs)		
	Yes	4	10
	No	36	90
5	Wearing tight stockings		
	Yes	-	-
	No	40	100
6	Types of foot wear		
	Flat sandals	39	97.5
	Open shoes	-	-
	Small heels	1	2.5
	Any others	-	-
7	Hours of rest taken		
	2 hrs	9	22.5
	More than 2 hrs	19	47.5
	Less than 2 hrs	12	30
8	Position assumed during sleep		
	Left lateral position	7	17.5
	Right lateral position	5	12.5
	Both	28	70
	Supine position	-	-
9	Timing of severity of edema		
	Morning	18	45
	Afternoon	10	25
	Evening	10	25
	Night	2	5
10	Travel daily		
	Yes	4	10
	No	36	90

Table 4.2.1 reveals that among 40 subjects, more than half of the subjects 31(77.5%) do not have any family history of any diseases and 9(22.5%) subjects have a family history of diabetes mellitus and take 2hrs of rest. More than half of the subjects 29(72.5%) have not had edema in previous pregnancy and 11(27.5%) subjects had edema in previous pregnancy.

Majority of the subject 36(90%)do not stand or sit for a long time and do not travel daily. 4(10%) stand or sit for a long time and travel daily. All of them40(100%) do not wear tight stockings. More than half of the subjects 39(97.5%) wear flat sandals and one(2.5%) subject wear small heels.

Most of the subjects 19(47.5%) take more than 2 hours of rest, and 12(30%) take less than 2hrs of rest. Majority of them 28(70%) sleep in both left lateral and right lateral position. 7(17.5%) sleep in left lateral position and 5(12.5%) subjects sleep in right lateral position.

Among 40 subjects, 18(45%) have severe edema in the morning. 10(25%) subjects each have severe degree of edema in the afternoon and another in the evening and 2(5%) have severe edema in the night.

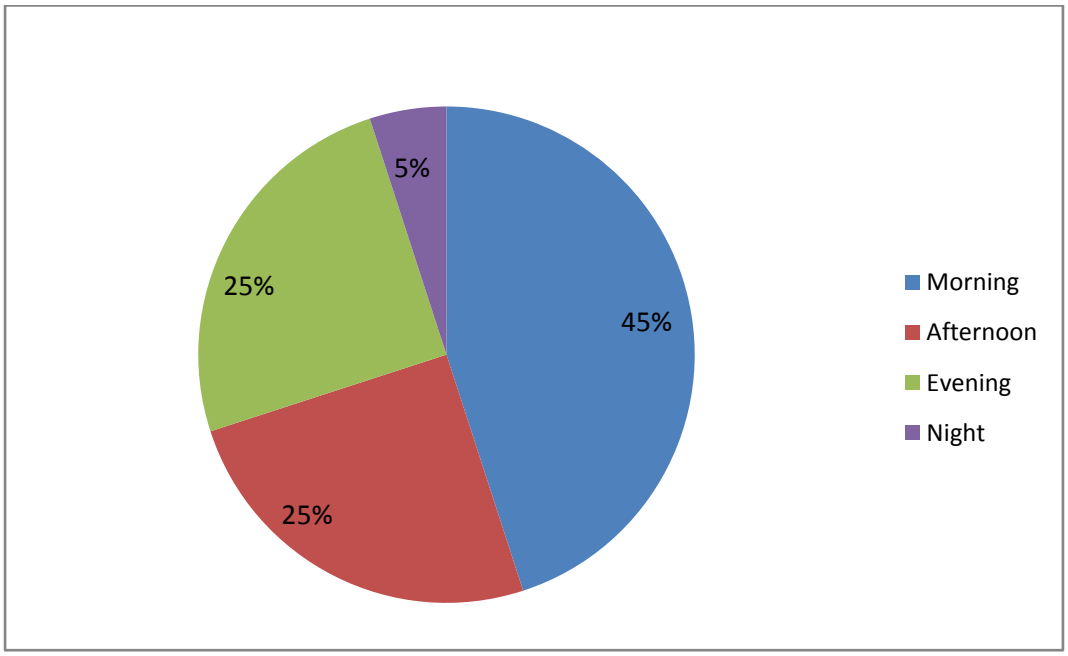

Figure 4.2.1 Pie diagram showing the timings of severity of physiological lower leg edema.

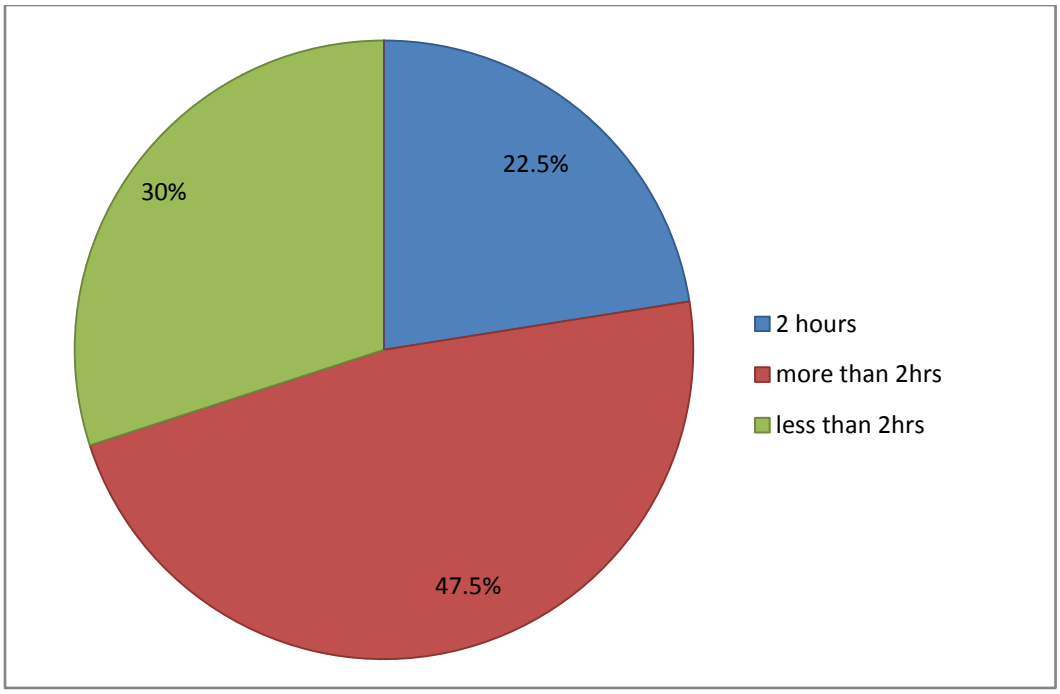

Figure 4.2.2 Pie diagram showing the hours of rest taken by the subjects with physiological lower leg edema

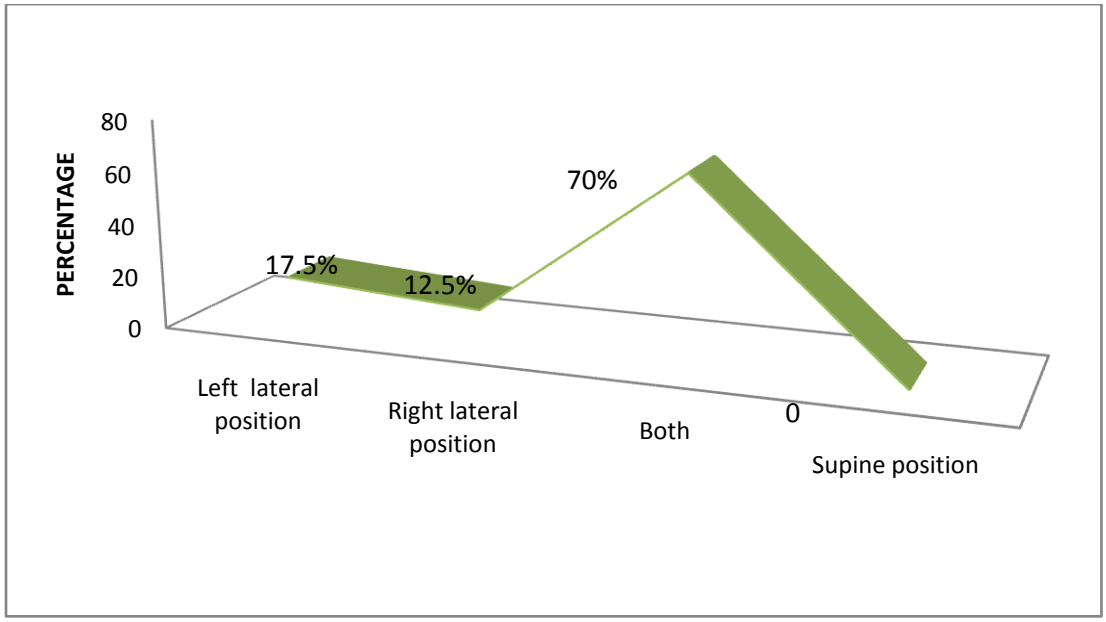

Fig 4.2.3 Line diagram showing the distribution of subjects on the basis of position during sleep

Table 4.2.2 Frequency and percentage distribution of subjects with dietary risk factors of physiological lower leg edema

S. No	Risk factors	Frequency (f)	Percentage (%)
1	**Dietary habits**		
	Vegetarian	-	-
	Non-vegetarian	-	-
	Both	40	100
2	**Coffee consumption**		
	Yes	33	82.5
	No	7	17.5
3	**Intake of water**		
	Less than 1 litre	-	-
	1-2 litre	14	35
	2-3 litre	25	62.5
	More than 3 litre	1	2.5
4	**Salt intake**		
	Less	-	-
	Normal	40	100
	More	-	-

Table4.2.2 reveals that among 40 subjects, majority of the subjects 33(82.5%) consumes coffee and the rest 7(17.5%) subjects do not consume coffee. All the subjects 40(100%) have both vegetarian and non-vegetarian and have normal salt intake. More than half of them 25(62.5%) drink 2-3litres of water. 14(35%) subjects take 1-2litre of water and one(2.5%) subject take more than 3 liters of water.

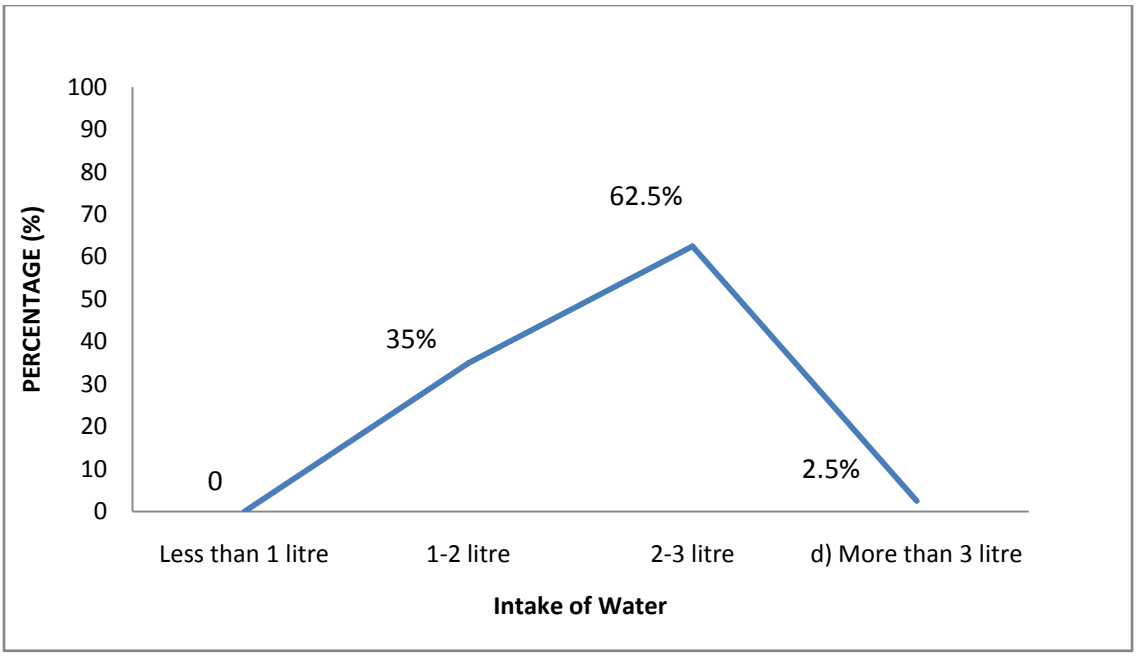

Fig 4.2.4 Line diagram showing the distribution subjects based on intake of water

Table 4.2.3 Frequency and percentage distribution of subjects according to measures taken to reduce physiological lower leg edema n=40

S. No	Measures taken to reduce edema	Frequency (f)	Percentage (%)
1	Foot elevation	30	75
2	Wearing compression stockings	-	-
3	Avoiding outdoor exercise	1	2.5
4	Applying cold compress	-	-
5	Wearing loose cotton clothes	1	2.5
6	Any others	-	-
7	None	8	20

Table4.2.3 reveals that more than half of the mothers 30(75%) use foot elevation as a measure to reduce edema. 8(20%) mothers do not take any measures to reduce edema. Only One (2.5%) subject avoided outdoor exercise and wear loose cotton clothes.

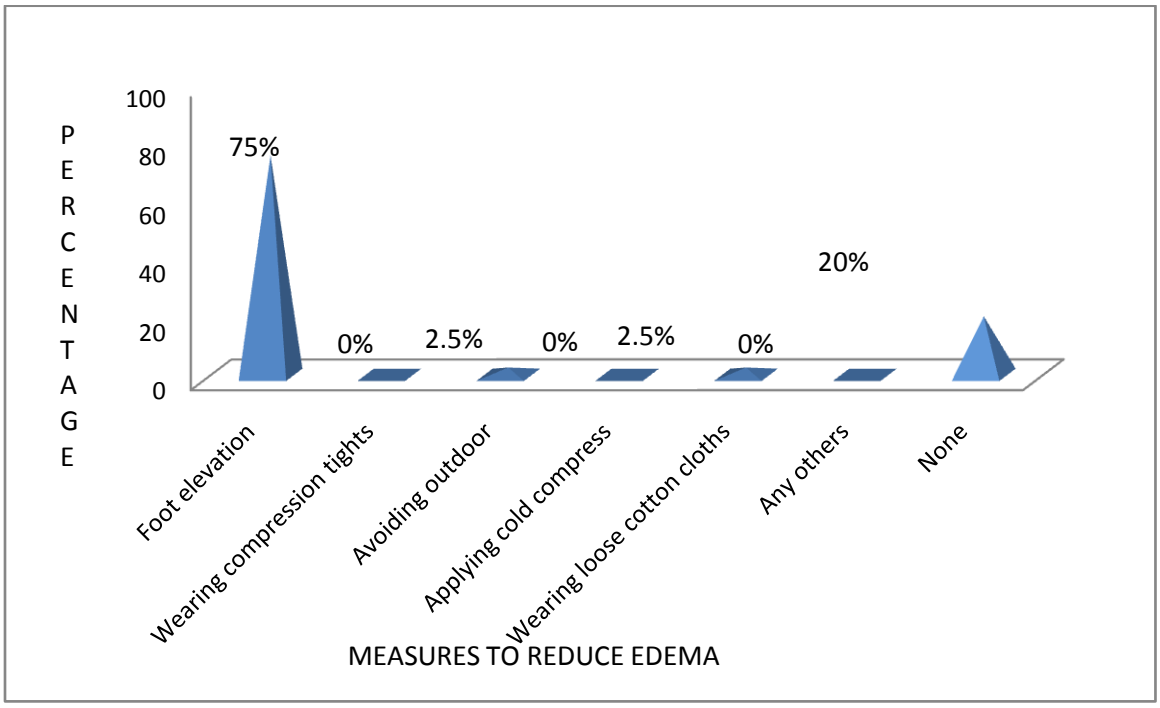

Fig 4.2.5 Clustered Pyramid diagram showing the distribution of subjects who use measures to reduce edema

Section4.3: Evaluation of effectiveness of leg massage over physiological lower leg edema

Table 4.3: Frequency and percentage distribution of subjects according to degree of physiological lower leg edema present among antenatal mothers.

n=40

S.No	Edema score	Interpretation	Pretest		Post test					
					Day1		Day2		Day 3	
			f	%	f	%	f	%	f	%
1	0	No edema	-	-	-	-	-	-	4	10%
2	1-6	Mild edema	-	-	2	5%	27	67.5%	36	90%
3	7-11	Moderate edema	23	57.5%	36	90%	13	32.5%	-	-
4	12-16	Severe edema	17	42.5%	2	5%	-	-	-	-

Table4.3 reveals that during pre test 23(57.5%) subjects had moderate edema. During post test Day1 most of the subjects 36(90%) had moderate physiological lower leg edema and 2(5%) had severe physiological lower leg edema and 2(5%) had mild edema. After leg massage for 3 days 36(90%) subjects had mild edema and 4(10%) subjects had no edema.

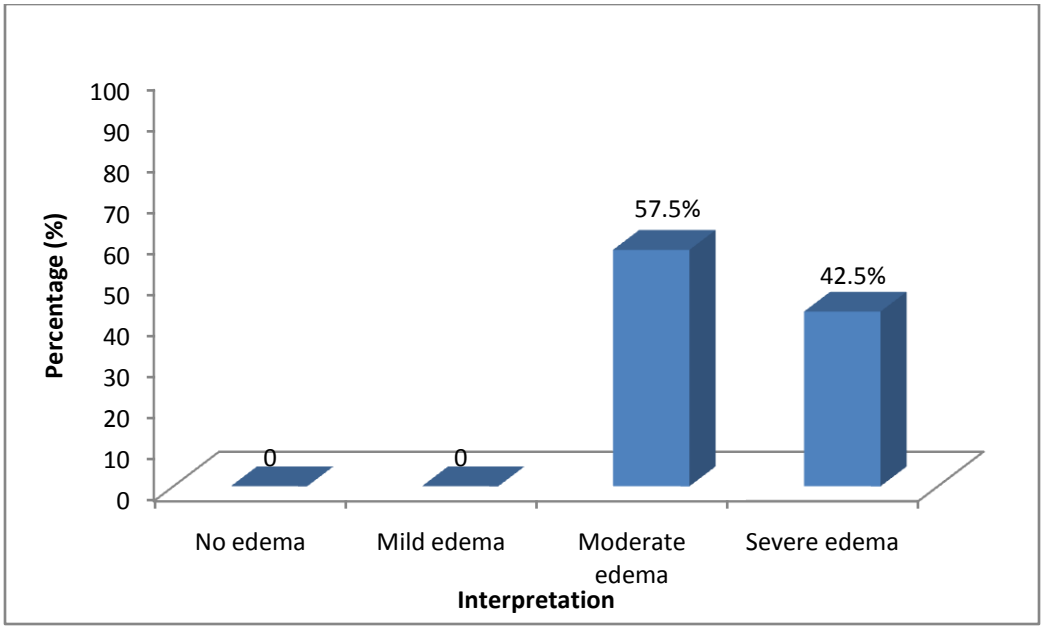

Fig 4.3.1 Clustered Cylinder diagram showing the pretest values of physiological lower leg edema

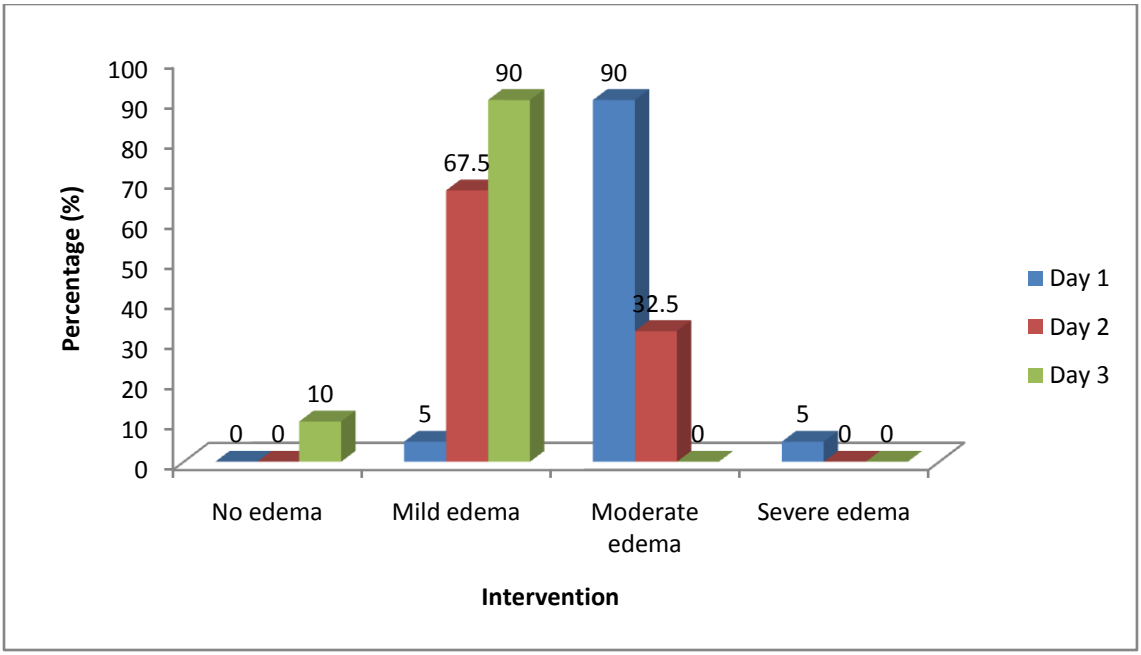

Fig 4.3.2 Clustered Column diagram shows the post test values of degree of physiological lower leg edema

Table 4.4: Comparison of mean and standard deviation of degree of physiological lower leg edema between pretest and post test scores among antenatal mothers using paired "t" test.

n=40

S. No.	No. of days	Mean	Standard deviation	Calculated "t" value	Tabulated value
1	Pre test	10.7	1.67		
2	Post test				
	Day 1	8.65	1.46	8.976*	1.69
	Day 2	6.15	1.03	22.31*	1.69
	Day 3	4.60	1.02	19.69*	1.69

Note- Statistically significant * p<0.05.

Table 4.4 shows that the pre test and post test in day1 (t=8.976 at p<0.05), pre test and post test of day2 (t=22.31 at p<0.05), pre test and post test of day 3 (t=19.69 at p<0.05). The calculated value of 't' is greater than tabulated value at 5% significance. Thus it is concluded that there is significant difference in the pre test and post test which indicates reduction of physiological lower leg edema among antenatal mothers after leg massage.

Table4.5.1: Association between pretest degrees of physiological lower leg edema with selected demographic variables n=40

Demographic variables	Intervention group				Df	Calculated $\chi 2$ value	Tabulated value
	Moderate		severe				
	f	%	f	%			
AGE							
20-28years	17	42.5	15	37.5	1	0.67 (NS)	6.31
29-37years	5	12.5	3	7.5			
EDUCATION							
Illiterate	-	-	-	-	4	0.050 (NS)	2.13
Primary	-	-	-	-			
Secondary	4	10	2	5			
Graduate	19	47.5	13	32.5			
Post graduate	1	2.5	1	2.5			
OCUPATION							
House-wife	19	47.5	14	35	1	0.23 (NS)	6.31
Employed	4	10	3	7.5			
AREA OF LIVING							
Urban	18	45	10	25	1	1.75 (NS)	6.31
Rural	5	12.5	7	17.5			
TYPE OF FAMILY							
Nuclear	20	50	12	30	1	1.63 (NS)	6.31
Joint	3	7.5	5	12.5			
HEIGHT							
141-150	7	17.5	5	12.5	4	1.43 (NS)	2.13
151-160	12	30	12	30			
161-170	4	10	0	-			
WEIGHT							
50-60	1	2.5	1	2.5	9	5.14*	1.83
61-70	15	37.5	5	12.5			
71-80	6	15	9	22.5			
81 and above	1	2.5	2	5			
BMI							
18.5-24.9	1	2.5	-	-	1	0.90 (NS)	6.31
25 and above	23	57.5	16	40			

Note-NS: Non significant at the level of p<0.05
***: Statistically significant**

Table 4.5.1 reveals that there is significant association between weight of the subject with physiological lower leg edema. There is no significant association between the demographic variables such as age, education, occupation, area of living, type of family, height, BMI with physiological lower leg edema except the weight of the study subjects. Hence the research hypothesis was accepted for weight of the subjects. The χ^2 value is 5.14 which is significant at the level of $p<0.05$.

Table 4.5.2: Association between pretest degrees of physiological lower leg edema with selected obstetrical variables

n=40

Demographic variables	Intervention group				Df	Calculated $\chi 2$ value	Tabulated value
	Moderate		Severe				
	f	%	f	%			
OBSTETRICAL SCORE							
Primi	12	30	13	32.5	1	0.46 (NS)	6.31
Multi	9	22.5	6	15			
GESTATIONAL WEEKS							
32-36weeks	13	32.5	5	12.5	1	0.88 (NS)	6.31
37-40weeks	10	25	12	30			

Note-NS: Non significant at the level of p<0.05

Table 4.5.2 shows that there is no significant association between the obstetric variables of obstetrical score and gestational weeks with physiological lower leg edema among antenatal mothers. Hence the research hypothesis was rejected. Thus the obstetrical variables does not have association with degree of physiological lower leg edema among antenatal mothers.

Table 4.5.3: Association between pretest degrees of physiological lower leg edema with selected biochemical profile n=40

Demographic variables	Intervention group				Df	Calculated $\chi 2$ value	Tabulated value
	Moderate		Severe				
	f	%	f	%			
BLOOD PRESSURE							
120/80	13	32.5	9	22.5	9	0.14 (NS)	1.83
140/90	-	-	-	-			
Less than 120/80	10	25	8	20			
SODIUM							
130-140	8	20	8	20	1	0.43 (NS)	6.31
More than 140	15	37.5	9	22.5			
HEMOGLOBIN							
9-11.9	7	17.5	8	20	1	0.28 (NS)	6.31
12-15	16	40	9	22.5			
BLOOD GLUCOSE							
Less than 80mg/dl	3	7.5	2	5	1	0.90 (NS)	6.31
80-120mg/dl	20	50	15	37.5			

Note-NS: Non significant at the level of p<0.05

Table 4.5.3 shows that there is no significant association between the biochemical parameters including blood pressure, sodium, hemoglobin, blood glucose with physiological lower leg edema. Hence the research hypothesis was rejected. Thus the biochemical parameters does not have association with degree of physiological lower leg edema among antenatal mothers.

Table 4.5.4: Association between pretest degrees of physiological lower leg edema with selected risk factors among intervention group

n=40

Risk factors	Intervention group				Df	Calculated X^2 value	Tabulated value
	Moderate		Severe				
	f	%	f	%			
Family history							
Diabetic mellitus	18	45	5	10	1	9.54*	3.84
None	5	12.5	12	30			
Lower leg edema in previous pregnancy							
Yes	6	15	5	12.5	1	0.05 (NS)	3.84
No	17	42.5	12	30			
Sitting for long time							
Yes	3	7.5	2	5	1	0.90 (NS)	3.84
No	20	50	15	37.5			
Standing for long time							
Yes	2	5	1	2.5	1	0.73 (NS)	3.84
No	21	52.5	16	40			
Types of footwear							
Flat sandals	22	55	16	40	1	0.04 (NS)	3.84
Small heels	1	2.5	1	2.5			
Hours of rest taken							
2hrs	4	10	4	10	2	0.50 (NS)	5.99
>2 hrs	12	30	7	17.5			
<2 hrs	7	17.5	6	15			
Position during sleep							
Left lateral position	3	7.5	5	12.5	2	1.92 (NS)	5.99
Right lateral position	2	5	2	5			
Both	18	45	10	25			

Note-NS: Non significant at the level of p<0.05

***: Statistically significant**

Table 4.5.4 reveals that there is significant association between family history of diabetes mellitus with physiological lower leg edema. There is no significant association between the risk factors such as lower leg edema in previous pregnancy, sitting, standing for long time, types of foot wear, rest hours, position of sleep with physiological lower leg edema except family history of diabetes mellitus. Hence the research hypothesis was accepted for the family history of diabetes mellitus.

Table 4.5.5: Association between pre test degrees of physiological lower leg edema with selected risk factors of severity and diet n=40

Risk factors	Intervention group				Df	Calculated X^2 value	Tabulated value
	Moderate		Severe				
	f	%	f	%			
Timing of severity of edema							
Morning	9	22.5	9	22.5	3	3.73 (NS)	7.81
Afternoon	8	20	2	5			
Evening	3	7.5	5	12.5			
Night	2	5	2	5			
Travel daily							
Yes	2	5	2	5	1	0.10 (NS)	3.84
No	21	52.5	15	37.5			
Coffee consumption							
Yes	3	7.5	6	15	1	2.77 (NS)	3.84
No	20	50	11	27.5			
Intake of water							
1-2litre	4	10	10	25	2	7.84*	5.99
2-3litre	18	45	6	15			
>3litre	1	2.5	1	2.5			

Note-NS: Non significant at the level of p<0.05

***: Statistically significant**

Table 4.5.5 reveals that there is significant association between intake of water for the antenatal mothers with physiological lower leg edema. There is no significant association between the other risk factors of diet and severity, travel and coffee consumption with physiological lower leg edema among antenatal mothers. Hence the research hypothesis was accepted for intake of water. Thus the risk factors related to diet and severity does not have association with degree of physiological lower leg edema among antenatal mothers.

CHAPTER V

RESULT AND DISCUSSION

This chapter deals with the detailed discussion based on the objectives with appropriate literature reviews, study findings. The purpose of the study was conducted to determine the effectiveness of leg massage on physiological lower leg edema among antenatal mothers admitted at selected hospitals, Coimbatore. The discussion brings the right report to closure. This is the most important section of any research report.

5.1: Distribution of risk factors of physiological lower leg edema among antenatal mothers.

The present study results that one of the major risk factor of physiological lower leg edema is coffee consumption among antenatal mothers. Among 40 samples, 33 antenatal mothers had coffee consumption each day which increases the degree of physiological lower leg edema. Thus it concludes that coffee consumption is a risk factor of physiological lower leg edema. It is supported with a similar study conducted by William (2014) on caffeine intake and the risk of physiological lower leg edema in pregnancy. Among the samples of lower leg edema occurred in women who ingested atleast 100mg of caffeine per day.

5.2: Effectiveness of leg massage in reduction of physiological lower leg edema among antenatal mothers by using paired 't' test

The present study reveals the post test mean on day 1 was 8.65 which had a decrease on day 2 with the mean of 6.15 and on the day 3 the mean value was 4.60. The obtained paired 't' test values (8.97) are higher than the tabulated value (1.69) ($P<0.05$) was highly significant. This concluded that there was a significant difference in the Pre test and post test I and II degree of physiological lower leg edema after leg massage, so the leg massage was highly effective in reducing degree of physiological lower leg edema. Another similar study was conducted by Khalilian (2014) to determine the effectiveness of leg massage in reducing physiological lower leg edema in mother admitted in antenatal Ward, CMC Vellore. Each mother was given 20 minutes of leg massage, pre and post-assessment of physiological lower leg edema was done using pitting edema scale. Results showed after leg massage the edema degree of 19 mothers (63.3%) were reduced from severe to moderate and for (6.6%) was reduced from moderate to

mild and for 9 mothers (30%) it remained in same level. A significant difference between pre and post nursing intervention in reduction of physiological lower leg edema for 30 samples ($p<0.01$). The study concluded that the leg massage is the best nursing intervention and it can be introduce into nursing curriculum as a best method of pain reduction.

5.3: Association between pretest degree of physiological lower leg edema with selected demographic variables among intervention group

The present study results shows that the chi square value was less than the table value for selected demographic variables like age, education, occupation, type of family , place of living, height, weight, BMI, obstertric score and gestational weeks at the level of $p<0.05$. Thus it concludes the selected demographic variables does not influence the physiological lower leg edema among antenatal mothers. So the leg massage was independently effective in reducing degree of physiological lower leg edema. Hence the research hypothesis was rejected. It is supported with a similar study conducted by Muller (2016) on impact of leg massage on the level of physiological lower leg edema among antenatal mothers and there is no association between degree of edema with the demographic variables.

CHAPTER - VI

SUMMARY AND CONCLUSION

This chapter gives a brief summary of the study, major findings, recommendations and the conclusion drawn. It also highlights the implications for nursing practice, nursing education, nursing administration and nursing research.

Edema is common during late pregnancy. It typically involves the lower extremities. Physiologic edema results from hormone-induced sodium retention which can be reduced by intermittently lying on the left side , by intermittently elevating the lower extremities, by wearing elastic compression stockings and by massage therapy.

Massage is the most widely used complementary therapy in nursing practice. Effective leg massage has many benefits as it provides tranquility and relaxation, improves circulation. The present study is a study to assess the effectiveness of leg massage on physiological lower leg edema among antenatal mothers at selected Hospital, Coimbatore. The main objective is to compare the degree of physiological lower leg edema among antenatal mothers between before and after administration of leg massage by using modified tool for assessment. The wide literature search also helped in selection of appropriate conceptual planning, developing frame work and research plan.

The research design used in this study was one group pre-test post-test design under pre experimental approach. The study was conducted in antenatal ward, of PSG Hospitals, Peelamedu, Coimbatore. The sampling technique used in this study was non probablity convienient sampling technique. The sample size was 40 and there was no control group. According to selection criteria, subjects were selected for the study. Questionnaire based on demographic variables and risk factors and modified Erwin edema tool was used to assess the degree of physiological lower leg edema among antenatal mothers. The data were collected after ethical approval. Pre test level of edema was assessed using modified Erwin edema scale and a questionnaire to assess the risk factors. Leg massage was given to the mothers who belong to intervention group. Post test day 1st, 2nd, 3rd the leg massage given for 20 minutes once in a day. Post test was done on each day 6 hours after intervention was given for three days.

The data was collected through interview and observation for all antenatal mothers who had physiological lower leg edema. Both descriptive and inferential statistics were used for analyses of the data. Student and independent "t" test was used to evaluate the effectiveness of leg massage and routine care. Chi square test was used to find out the association between degree of physiological lower leg edema among antenatal mothers and their demographic variables.

6.1 Major findings

- Among 40 mothers, most of them 32 (80%) were in the age group of 20 - 28 years and 8(20%) was in the age group of 29-37 years.
- Among 40 mothers, 6 (15%) had secondary school education and 32(80%) were graduates.
- Among 40 mothers, 33 mothers (82.5%) were house wife.
- Among 40 mothers 25(62.5%) was primi gravid mothers while 15(37.5%) was multi para mothers.
- The level of physiological lower leg edema among antenatal mothers, 17(42.5%) had severe physiological lower leg edema on the pre test assessment and 23(57.5%) mothers had moderate physiological lower leg edema
- Leg massage was effective and complementary in reduction in the degree of physiological lower leg edema ($p<0.005$) in the group.
- There was no significant association between the pretest level of physiological lower leg edema in selected demographic variables like age, education, occupation, area of living, type of family and place of living, BMI, height, weight. Biochemical parameters like blood pressure, sodium level, hemoglobin level and blood glucose levels and risk factors like family history , presence of lower leg edema in previous pregnancy , sitting for long time , standing for long time , wearing tight stockings , types of footwear , hours of rest taken , position during sleep , timing of severity , travelling , dietary habits , coffee consumption , intake of water , salt intake

6.2 Conclusion:

- The study findings concludes that leg massage is an effective, inexpensive method in reducing the degree of physiological lower leg edema among antenatal mothers. Leg

massage should become a routine activity among antenatal mothers with physiological lower leg edema. The present study was intended to evaluate the effectiveness of leg massage on physiological lower leg edema among antenatal mothers at selected Hospital, Coimbatore.

6.3 Nursing implications:

The present study has implications for nursing practice, nursing education, nursing administration and nursing research.

6.3.1 Nursing practice:

- Nurses can implement the practice of leg massage in reducing physiological lower leg edema among antenatal mothers in clinical and community settings.
- Nurses can assess the physiological lower leg edema using pitting edema scale on daily basis.
- Nurses can involve in educating antenatal mothers with physiological lower leg edema and their families on the importance of leg massage in reducing physiological lower leg edema

6.3.2 Nursing education:

- The nursing curriculum should be updated with evidence based nursing research on leg massage in reducing the physiological lower leg edema among antenatal mothers.
- Continuing nursing education and nursing educational conferences among staff nurses will help to promote and update their knowledge on administration of leg massage for reducing physiological lower leg edema among antenatal mothers.
- Workshops should be organized about the effect of leg massage on physiological lower leg edema among antenatal mothers.

6.3.3 Nursing administration:

- Provision should be made for staff working in antenatal ward to get training in leg massage.

- Nursing administrators need to facilitate the utilization of research based nursing intervention such as leg massage in the management of physiological lower leg edema among antenatal mothers.

6.3.4 Nursing research:

- The study can be a baseline for further studies related to lower leg edema.
- A survey research can be conducted about the satisfaction of nurses and family members regarding leg massage on physiological edema reduction.

6.4 Limitations

The researcher did not experience any short comings/ problems during the course of the study

6.5 Recommendation for future study:

- ❑ The same study can be done with control group.
- ❑ A comparative study can also be done to assess the effectiveness of foot elevation versus leg massage on lower leg edema among antenatal mothers.

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ANNEXURE-I

From

Ms. Dona Sara Philipose,

M. Sc Nursing I Year,

PSG College of Nursing,

Coimbatore – 04.

To

Member-Secretary,

Institutional Human Ethics Committee,

PSG Institute of Medical Sciences & Research,

Coimbatore – 04.

Madam,

Sub: Ethical review of study proposal by IHEC – request for – reg.

I hereby enclose all answers for ethical review questions.

Title of the proposed study:

Effectiveness of foot massage on physiological lower leg among antenatal mothers admitted at selected hospital, Coimbatore.

Name of the Principal Investigator: Ms. Dona Sara Philipose

Name of the subject guide : Dr. A Jayasudha

Thanking you,

Date: 25/7/17

Signature of Principal Investigator

From

Ms. Dona Sara Philipose,
M.Sc Nursing I Year,
PSG College of Nursing,
Coimbatore – 04.

To

The HOD of OBG Department,
PSG Hospitals,
Coimbatore – 04.

Through: The Principal, PSG College of Nursing.

Respected Sir/Madam

Sub: Seeking permission to conduct the study among

Antenatal mothers at selected hospital , Antenatal ward.

I Ms.Dona, I year M.Sc Nursing student is interested in doing this study titled , **"EFFECTIVENESS OF FOOT MASSAGE ON PHYSIOLOGICAL LOWER LEG EDEMA AMONG ANTENATAL MOTHERS ADMITTED AT SELECTED HOSPITAL IN COIMBATORE".** Kindly grant me permission to carry out the study in PSG Hospital, Antenatal ward.

Thank you,

Date: 12/7/17

Yours sincerely:

Place: Coimbatore.

Ms. Dona Sara Philipose,

M. Sc Nursing I-year.

Permitted

Signature of the HOD of The Department:

PSG COLLEGE OF NURSING, COIMBATORE-4.

Ref.No: CN/I/103/17

Date: 04.07.2017

To

The Dean
PSG IMSR&H
Peelamedu
Coimbatore.

Respected Sir,

Sub: Permission to conduct research req.reg

Warm Greetings!

This is to inform you that Ms. Dona Sara Philipose, I year M.Sc Nursing student of our College of Nursing, Coimbatore is planning to conduct a study on

"A Study to Assess the Risk Factors of Physiological Lower Leg Edema and the Effectiveness of Foot Massage on Physiological Lower Leg Edema among Antenatal Mothers Admitted in a Tertiary Care Setting, Coimbatore"

as part of M.Sc(N) research requirement to be submitted at The Tamilnadu Dr. M.G.R Medical University, Chennai.

Kindly grant her permission for conducting pilot & Main study in our Hospital. We assure you that the study will be conducted without disturbing the routine activities of the Hospital.

Thanking you,

Dr. A. JAYASUDHA
PRINCIPAL

PSG COLLEGE OF NURSING ★ Peelamedu ★ COIMBATORE-4

Cc to: The HOD, OG ward
The Nursing Superintendent

ANNEXURE-II

PSG Institute of Medical Sciences & Research
Institutional Human Ethics Committee
Recognized by The Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)
POST BOX NO. 1674, PEELAMEDU, COIMBATORE 641 004, TAMIL NADU, INDIA
Phone : 91 422 - 2598822, 2570170, Fax : 91 422 - 2594400, Email : ihec@psgimsr.ac.in

Ms Dona Sara Philipose
I M Sc Nursing
Guide: Dr A Jayasudha
PSG College of Nursing
Coimbatore

Ref: Project No.17/239

Date: October 24, 2017

Dear Ms Dona Sara,

Institutional Human Ethics Committee, PSG IMS&R reviewed and discussed your application dated 27.07.2017 to conduct the research study entitled "*Effectiveness of leg massage on physiological lower leg edema among antenatal mothers admitted at selected hospital, Coimbatore*" during the IHEC meeting held on 04.08.2017.

The following documents were reviewed and approved:

1. Project submission form
2. Study protocol (Version 1 dated 27.07.2017)
3. Informed consent form - English (Version 2 dated 19.10.2017)
4. Informed consent form - Tamil (Version 2 dated 22.09.2017)
5. Data collection tool – English (Version 2 dated 22.09.2017)
6. Data collection tool – Tamil (Version 2 dated 19.10.2017)
7. Permission letter from the Dean and concerned Head of Department
8. Current CVs of Principal investigator, Co-investigator
9. Budget

The following members of the Institutional Human Ethics Committee (IHEC) were present at the meeting held on 04.08.2017 at IHEC Secretariat, PSG IMS & R between 10.00 am and 11.00 am:

Sl. No.	Name of the Member of IHEC	Qualification	Area of Expertise	Gender	Affiliation to the Institution Yes/No	Present at the meeting Yes/No
1	Mr R Nandakumar (Chairperson, IHEC)	BA., BL	Legal Expert	Male	No	Yes
2	Dr. S. Bhuvaneshwari (Member-Secretary, IHEC)	MD	Clinical Pharmacology	Female	Yes	Yes
3	Dr S Shanthakumari	MD	Pathology	Female	Yes	Yes
4	Dr Sudha Ramalingam	MD	Epidemiologist Alt. member-Secretary	Female	Yes	Yes
5	Dr D Vijaya	M Sc., Ph D	Basic Medical Sciences (Biochemistry)	Female	Yes	Yes

The study is approved in its presented form. The decision was arrived at through consensus. Neither PI nor any of proposed study team members were present during the decision making of the IHEC. The IHEC functions in accordance with the ICH-GCP/ICMR/Schedule Y guidelines. The approval is valid until one year from the date of sanction. You may make a written request for renewal / extension of the validity, along with the submission of status report as decided by the IHEC.

PSG Institute of Medical Sciences & Research
Institutional Human Ethics Committee

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Following points must be noted:

1. IHEC should be informed of the date of initiation of the study
2. Status report of the study should be submitted to the IHEC every 12 months
3. PI and other investigators should co-operate fully with IHEC, who will monitor the trial from time to time
4. At the time of PI's retirement/intention to leave the institute, study responsibility should be transferred to a colleague after obtaining clearance from HOD, Status report, including accounts details should be submitted to IHEC and extramural sponsors
5. In case of any new information or any SAE, which could affect any study, must be informed to IHEC and sponsors. The PI should report SAEs occurred for IHEC approved studies within 7 days of the occurrence of the SAE. If the SAE is 'Death', the IHEC Secretariat will receive the SAE reporting form within 24 hours of the occurrence
6. In the event of any protocol amendments, IHEC must be informed and the amendments should be highlighted in clear terms as follows:
   a. The exact alteration/amendment should be specified and indicated where the amendment occurred in the original project. (Page no. Clause no. etc.)
   b. Alteration in the budgetary status should be clearly indicated and the revised budget form should be submitted
   c. If the amendments require a change in the consent form, the copy of revised Consent Form should be submitted to Ethics Committee for approval
   d. If the amendment demands a re-look at the toxicity or side effects to patients, the same should be documented
   e. If there are any amendments in the trial design, these must be incorporated in the protocol, and other study documents. These revised documents should be submitted for approval of the IHEC and only then can they be implemented
   f. Any deviation-Violation/waiver in the protocol must be informed to the IHEC within the stipulated period for review
7. Final report along with summary of findings and presentations/publications if any on closure of the study should be submitted to IHEC

Kindly note this approval is subject to ratification in the forthcoming full board review meeting of the IHEC.

Thanking You,

Yours Sincerely,

SECRETARY
PSG IMS&R
COIMBATORE-641004
INSTITUTIONAL HUMAN ETHICS COMMITTEE

Dr D Vijaya
Member - Secretary
Institutional Human Ethics Committee

ANNEXURE-III

PSG Institute of Medical Science and Research, Coimbatore
Institutional Human Ethics Committee
INFORMED CONSENT FORMAT FOR RESEARCH PROJECTS

I Ms. Dona carrying out a study on the topic: Effectiveness of leg massage on physiological lower leg edema among antenatal mothers admitted at selected hospital , Coimbatore.

as part of my / our research project being carried out under the aegis of the Department of Maternity Nursing.

(*Applicable to students only*): My / our research guide is: Dr. A. Jayasudha

The justification for this study is: Physiological lower leg edema is one of the cutaneous manifestations of pregnancy. The weight gain during pregnancy and gravity slow down in circulation of blood and body fluids particularly in the lower limbs. The swelling or edema is a very common discomfort of pregnancy .It is estimated that about 75% of women experience this excessive accumulation of fluid around the legs and ankles during pregnancy. Many women find the current available methods unsatisfactory and are looking for other effective and safe options.

Only a few studies have been conducted on the care of this very common condition. Some studies have examined the effects of foot reflexology on reducing edema. However, definitive effects of these methods have not been verified through clinical trials, and more extensive studies are still required in this area.

The objectives of this study are:

- To identify the risk factors of physiological lower leg edema among antenatal mothers.
- To determine the effectiveness of foot massage on physiological lower leg edema among antenatal mothers.
- To associate the pre test level of physiological lower leg edema among antenatal mothers with selected demographic variables and risk factors.

Sample size: convenient sampling technique.

Estimated sample size is 40.

Study volunteers / participants are (specify population group & age group):
Antenatal mothers after second trimester who fulfill inclusion criteria from Antenatal ward.
Those mothers who come under the age group of 20-35 years.

Location: Antenatal ward, PSG Hospital, Coimbatore.

I request you to kindly cooperate with me in this study. I propose to collect background information and other relevant details related to this study. I will be carrying out the study from ____ to____.

Initial interview (specify approximate duration) : 20 minutes.

Data will be collected and stored for a period of 3 years. I will not use the data as part of another study.

Blood sample collection: Not applicable

Health education sessions:
Number of sessions: Not applicable
Approximate **duration** of each session: Not applicable

Clinical examination (Specify details and purpose): Edema tool is used to assess the degree of physiological lower leg edema.

Final interview (specify approximate duration): 20minutes

Benefits from this study: To see the effectiveness of foot massage in reducing physiological lower leg edema among antenatal mothers.

Risks involved by participating in this study: No risk.

How the **results** will be used:

1. To perform evidence based practice
2. Submission in the thesis.
3. To publish in the journals and conference presentation.

If you are uncomfortable in answering any of our questions during the course of the interview / biological sample collection, **you have the right to withdraw from the interview / study at anytime.** You have the freedom to withdraw from the study at any point of time. Kindly be assured that your refusal to participate or withdrawal at any stage, if you so decide, will not result in any form of compromise or discrimination in the services offered nor would it attract any penalty. You will continue to have access to the regular services offered to a patient. You will **NOT** be paid any remuneration for the time you spend with us for this interview / study. The information provided by you will be kept in strict confidence. Under no circumstances shall we reveal the identity of the respondent or their families to anyone. The information that we collect shall be used for approved research purposes only. You will be informed about any significant new findings - including adverse events, if any, – whether directly related to you or to other participants of this study, developed during the course of this research which may relate to your willingness to continue participation.

Consent: The above information regarding the study, has been read by me/ read to me, and has been explained to me by the investigator/s. Having understood the same, I hereby give my consent to them to interview me. I am affixing my signature / left thumb impression to indicate my consent and willingness to participate in this study (i.e., willingly abide by the project requirements).

Signature / Left thumb impression of the Study Volunteer / Legal Representative:

Signature of the Interviewer with date: Witness:

Contact number of PI: **7395865670**

Contact number of Ethics Committee Office: 0422 2570170 Extn : 5818

பூ. சா. கோ மருத்துவக் கல்லூரி மற்றும் ஆராய்ச்சி நிறுவனம், கோவை

மனித நெறிமுறைக் குழு

ஒப்புதல் படிவம்

தேதி:

டோனா சாரா ஃபிலிபோஸ், ஆகிய நான் பூ. சா. கோ மருத்துவக் கல்லூரியின் / மருத்துவமனையின் மகப்பேறு மருத்துவத் துறையின் கீழ், **"கர்ப்பிணிப் பெண்களிடையே ஏற்படும் கால் வீக்கத்திற்கு கால்களை இதமாக தடவி விடுதல் திறனுள்ளதா"** என்ற தலைப்பில் ஆய்வு மேற்கொள்ள உள்ளேன்.

என் ஆய்வு வழிகாட்டி: திருமதி. முனைவர். A. ஜெயசுதா

ஆய்வு மேற்கொள்வதற்கான அடிப்படை:

பிரசவத்தின் போது ஏற்படும் கால் வீக்கம் கர்ப்பிணிப் பெண்கள் மத்தியில் அதிகரித்து வருகிறது.

ஆய்வின் நோக்கம்:

1. கர்ப்பிணிப் பெண்களுக்கு ஏற்படும் கால் வீக்கத்திற்கான காரணங்களைக் கண்டறிதல்.
2. கர்ப்பிணிப் பெண்களிடையே ஏற்படும் கால் வீக்கத்திற்கு கால்களை இதமாக தடவி விடுதல் என்னும் ஆய்வு திறனுள்ளதா என்பதை கண்டறிதல்.
3. கர்ப்பிணிப் பெண்களிடையே ஏற்படும் கால் வீக்கத்திற்கும், புள்ளி விவர மாதிரிகளுக்கும் இடையில் ஏதேனும் தொடர்பு உள்ளதா என்பதைக் கண்டறிதல்.

ஆய்வில் பங்கு பெறும் நபர்களின் எண்ணிக்கை: 40

ஆய்வில் பங்கு பெறுவோரின் வயது மற்றும் இதர குறிப்புகள்: 20-35 வயதிற்குட்பட்ட, கால் வீக்கத்துடன் கூடிய, இரண்டாவது மூன்று மாதகால நிலையில் உள்ள கர்ப்பிணிப் பெண்கள்.

ஆய்வு மேற்கொள்ளும் இடம்: கர்ப்பிணிப் பெண்கள் பிரிவு, பூ. சா. கோ. மருத்துவமனை, கோயம்புத்தூர்.

இந்த ஆய்வில் எங்களுடன் ஒத்துழைக்குமாறு கேட்டுக்கொள்கிறோம். நாங்கள் சில தகவல்களை இந்த ஆய்விற்காக சேகரிக்க உள்ளோம்.

ஆய்வு செய்யப்படும் முறை:

1. கேள்வி கேட்டல் / வினா வினவுதல் (அடிப்படை தகவல்கள் குறித்து)
2. கால்களை இதமாக தடவி விடுவதன் மூலம் கால் வீக்கத்தை குறைத்தல்.

முதன்மை நேர்காணல்: 20 நிமிடங்கள்

இந்த ஆய்வில் கிடைக்கும் தகவல்கள் **3 வருடங்கள்** பாதுகாக்கப்படும். இந்த தகவல்கள் வேறு ஆய்விற்குப் பயன்படுத்தப் பட மாட்டாது.

சுகாதாரக் கல்வி: அமர்வுகள்: வாரத்திற்கு ___ முறை ஒரு அமர்வுக்கான நேரம்: ___ நிமிடங்கள்
மருத்துவ பரிசோதனைகள்: உண்டு

இரத்த மாதிரி சேகரிப்பு: இல்லை

இரத்த மாதிரி எடுப்பது வழக்கமான சிகிச்சைக்காகவோ அல்லது இந்த ஆய்விற்காகவோ:
பொருந்தாது

இதனால் ஏற்படக் கூடிய அசௌகரியங்கள் / பக்க விளைவுகள்: இதனால் எந்த அசௌகரியமோ, பக்க விளைவுகளோ ஏற்படாது.

இரத்த மாதிரிகள் ஆய்விற்குப் பின் பாதுகாத்து வைக்கப்படுமா? ஆம் / இல்லை, அழிக்கப்படும்: **பொருந்தாது**

சேகரிக்கப்பட்ட இரத்தம் விற்கப்படுமா? ஆம் / இல்லை **பொருந்தாது**

சேகரிக்கப்பட்ட இரத்தம் வேறு நிறுவனத்துடன் பகிர்ந்து கொள்ளப்படுமா? ஆம் / இல்லை: **பொருந்தாது**

மருந்துகள் ஏதேனும் கொடுக்கப்படவிருந்தால் அவை பற்றிய விவரம் (கொடுக்கப்படும் காரணம், காலம், பக்க விளைவுகள், பயன்கள்): **பொருந்தாது**

மருந்துகள் கொடுக்கப்படுவது வழக்கமான சிகிச்சை முறையா?: ஆம் / இல்லை (இல்லை என்றால் கொடுக்கப்படும் காரணம்) **பொருந்தாது**

கொடுக்கப்படும் மருந்துகளுக்கு மாற்று உள்ளதா?: ஆம் / இல்லை (ஆம் என்றால் இந்த குறிப்பிட்ட மருந்து கொடுக்கப்படும் காரணம்) **பொருந்தாது**

ஆய்வில் பங்குபெறுவதால் ஏற்படும் பலன்கள்:

கர்ப்பிணிப் பெண்களிடையே ஏற்படும் கால் வீக்கத்திற்கு கால்களை இதமாக தடவி விடுவதால் கால் வீக்கம் குறைய வாய்ப்பு உள்ளது.

ஆய்வினால் பங்கேற்பதால் ஏற்படும் அசௌகரியங்கள் / பக்க விளைவுகள்: இந்த ஆய்வினால் தங்களுக்கு எந்த விதமான அபாயங்களும் அசௌகரியங்களும் ஏற்படாது.

ஆய்வின் முடிவுகள் எந்த முறையில் பயன்படுத்தப்படும்?

1. முதுகலைப் பட்டத்திற்காக பல்கலைகழகத்திற்கு அனுப்பப்படும்.
2. செவிலியர் துறை சார்ந்த இதழ்களில் பிரசுரிக்கப்படும்.
3. ஆதாரப்பூர்வமான பயிற்சிக்கு அடித்தளமிடும்

இந்த ஆய்வின் கேள்விகளுக்கு பதிலளிப்பதோ, இரத்த மாதிரிகள் அல்லது திசு மாதிரிகள் எடுப்பதிலோ உங்களுக்கு ஏதேனும் அசௌகரியங்கள் இருந்தால், எந்த நேரத்தில் வேண்டுமானாலும் ஆய்விலிருந்து விலகிக்கொள்ளும் உரிமை உங்களுக்கு உண்டு. ஆய்விலிருந்து விலகிக்கொள்வதால் உங்களுக்கு அளிக்கப்படும் சிகிச்சை முறையில் எந்த வித பாதிப்பும் இருக்காது என்று உங்களுக்கு உறுதியளிக்கிறோம். மருத்துவ மனையில் நோயாளிகளுக்கு அளிக்கப்படும் சேவைகளை நீங்கள் தொடர்ந்து பெறலாம். இந்த ஆய்வில் பங்கேற்க ஒப்புக்கொள்ளுவதால் வேறு எந்த விதமான கூடுதலான பலனும் உங்களுக்குக் கிடைக்காது. நீங்கள் அளிக்கும் தகவல்கள் இரகசியமாக வைக்கப்படும். ஆய்வில் பங்கேற்பவர்கள் பற்றியோ அவர்கள் குடும்பத்தைப் பற்றியோ எந்தத் தகவலும் எக்காரணம் கொண்டும் வெளியிடப்படாது என்று உறுதியளிக்கிறோம். நீங்கள் அளிக்கும் தகவல்கள் / இரத்த மாதிரிகள் / திசு மாதிரிகள் அங்கீகரிக்கப்பட்ட ஆய்விற்கு மட்டுமே பயன்படுத்தப்படும். இந்த ஆய்வு நடைபெறும் காலத்தில் குறிப்பிடத்தகுந்த புதிய கண்டுபிடிப்புகள் அல்லது பக்க விளைவுகள் ஏதும் ஏற்பட்டால் உங்களுக்குத் தெரிவிக்கப்படும். இதனால் ஆய்வில் தொடர்ந்து பங்கு பெறுவது பற்றிய உங்கள் நிலைப்பாட்டை நீங்கள் தெரிவிக்க ஏதுவாகும்.

ஆய்வுக்குட்படுபவரின் ஒப்புதல்: இந்த ஆய்வைப் பற்றிய மேற்கூறிய தகவல்களை நான் படித்து அறிந்து கொண்டேன் / ஆய்வாளர் படிக்கக் கேட்டுத் தெரிந்து கொண்டேன். ஆய்வினைப் பற்றி நன்றாகப் புரிந்து கொண்டு இந்த ஆய்வில் பங்கு பெற ஒப்புக்கொள்கிறேன். இந்த ஆய்வில் பங்கேற்பதற்கான எனது ஒப்புதலை கீழே கையொப்பமிட்டு, கை ரேகை பதித்து நான் தெரிவித்துக் கொள்கிறேன்.

பங்கேற்பாளரின் பெயர், முகவரி:

பங்கேற்பாளரின் கையொப்பம் / கை ரேகை / சட்டப்பூர்வ பிரதிநிதியின் கையொப்பம்:

தேதி :

ஆய்வாளரின் கையொப்பம்:
தேதி :

ஆய்வாளரின் தொலைபேசி எண்: 7395865670
மனித நெறிமுறைக் குழு அலுவலகத்தின் தொலைபேசி எண்: 0422-2570710 Extn.: 5818

ANNEXURE IV

SECTION A

Demographic data

1. Sample number
2. Age in years
3. Educational status
    a. Illiterate
    b. Primary education
    c. Secondary education
    d. Graduate
    e. Post graduate
4. Occupation
    a. House wife
    b. Employed

    If employed, type of work

        i. Sedentary
        ii. Moderate
        iii. Heavy

5. Type of family
    a. Nuclear family
    b. Joint family
    c. Extended family
6. Area of living
    a. Urban area
    b. Rural area
7. Height
    a. 130 – 140cm
    b. 141 – 150cm
    c. 151 – 160cm
    d. 161 – 170cm

8. Weight
    a. 50 – 60kg
    b. 61 – 70kg
    c. 71 – 80kg
    d. more than 80kg
9. BMI
    a. Less than 18.5 (underweight)
    b. 18.5 – 24.9
    c. More than 25 (overweight)

Obstetrical history

1) Obstetric score
   G P L A

2) Gestational age

3) Do you have lower leg edema
    a. Yes
    b. No
    If yes , specify

SECTION B

Physical, physiological and biochemical parameters of antenatal mother

1) Blood pressure
    a. 120/80mmHg
    b. 140/90mmHg
    c. More than 140/90mmHg
    d. Less than 120/80mmHg

2) Abdominal girth

3) Fundal height

4) Sodium level
    a. 130 – 140 mEq/L
    b. More than 140 mEq/L
    c. Less than 130mEq/L
5) Haemoglobin level
    a. 6 – 8.9gm/dl
    b. 9 – 11.9gm/dl
    c. 12 – 15gm/dl
6) Blood glucose level
    a. Less than 80mg/dl
    b. 80 – 120mg/dl
    c. More than 120mg/dl
7) Urine Albumin level
    a. Less than 35gm/l
    b. 35 – 50gm/l
    c. more than 50gm/l

Assessment of risk factors and management of physiological lower leg edema

1) Family history
    a. Diabetes mellitus
    b. Hypertension
    c. Cardiac diseases
    d. None
2) Presence of lower leg edema in previous pregnancy
    a. Yes
    b. No

    If yes , from which month of pregnancy
3) Sitting for a prolonged period (more than 4 hours)
    a) Yes
    b) No

    If yes , then how much time.

4) Standing for a prolonged period (more than 4 hours)
    a. Yes
    b. No
    c. If yes, then how much time.
5) Wearing tight stockings
    a. Yes
    b. No
    If yes, specify
6) Type of footwear
    a. Flat sandals
    b. Open shoes
    c. With small heels
    d. Any others , specify
7) Hours of rest taken in the afternoon
    a. 2 hours
    b. More than 2 hours
    c. Less than 2 hours
8) Position assumed during sleep
    a. Left lateral position
    b. Right lateral position
    c. Supine position
9) Timing of severity of edema
    a. Morning
    b. Afternoon
    c. Evening
    d. Night
10) Travel daily
    a. Yes
    b. No
    If yes how long and how far.

11) Dietary habits

a. Vegetarian
b. Non-vegetarian
c. Both

12) Coffee consumption

a. Yes
b. No

If yes, how many times per day

13) Intake of water

a. Less than 1 liter
b. 1 – 2 liters
c. 2 – 3 liters
d. More than 3 liters

14) Salt intake in diet

a. Less
b. Normal
c. more

15) Any other measures followed to reduce edema

a. Foot elevation
b. Wearing compression tights
c. Avoiding outdoors during hot climate
d. Applying cold compress or oil massages
e. Wearing loose and cotton clothes
f. Any leg exercises
g. Any others, specify

பகுதி - அ

I. புள்ளி விவர மாதிரிகள்:

1. ஆய்வில் பங்கேற்பவரின் வரிசை எண்:
2. வயது:
3. கல்வித் தகுதி:
    a. படிப்பின்மை
    b. ஆரம்பக் கல்வி
    c. மேல்நிலைக் கல்வி
    d. பட்டப் படிப்பு
    e. முதுகலைப் படிப்பு
4. வேலைத் தகுதி:
    a. இல்லத்தரசி
    b. வேலை செய்பவர், ஆம் எனில் எந்த விதமான வேலை
        i. உடல் உழைப்பு தேவைப்படாத வேலை
        ii. மிதமான உடல் உழைப்பு வேலை
        iii. உடல் உழைப்பு அதிகமான வேலை
5. குடும்பத்தின் வகை:
    a. தனிக் குடும்பம்
    b. கூட்டுக் குடும்பம்
    c. நீட்டிக்கப்பட்ட குடும்பம்
6. வசிக்கும் இடம்:
    a. நகர்புற பகுதி
    b. கிராமப்புற பகுதி
7. உயரம்
    a. 130-140 செ.மீ
    b. 141-150 செ.மீ
    c. 151-160 செ.மீ
    d. 161-170 செ.மீ
8. எடை
    a. 50-60 கிலோ
    b. 61-70 கிலோ
    c. 71-80 கிலோ
    d. 81 கிலோவிற்கு மேல்

9. உடல் நிறை குறியீட்டெண்:
    a. 18.5 குறைவாக
    b. 18.5-24.9
    c. 25க்கு மேல்

II. மகப்பேறியல் விவரங்கள்

1. மகப்பேறு தன்மை

    G P L A

2. கர்ப்பகால வயது:
3. கால் வீக்கம் உண்டா:
    a. ஆம்
    b. இல்லை

பகுதி - ஆ

கர்ப்பிணிப்பெண்களின் உடல், உடலியல் மற்றும் உயிர்வேதியியல் சார்ந்த அளவுருக்கள்:

1. இரத்த அழுத்தம்:
    a. 120/80 மி.மீ/மெர்குரி
    b. 140/90 மி.மீ/மெர்குரி
    c. 140/90 க்கும் அதிகமான
    d. 120/80 க்கும் குறைவான
2. வயிற்றின் சுற்றளவு:
3. கர்ப்பப் பையின் உயரம்:
4. சோடியத்தின் அளவு:
    a. 130-140 mEq/L
    b. 140 mEq/L அதிகமாக
    c. 130 mEq/L குறைவாக
5. இரத்தத்தின் அளவு:
    a. 6-8.9 gm/dl
    b. 9-11.9 gm/dl
    c. 12-15 gm/dl
6. சர்க்கரையின் அளவு:
    a. 80 mg/dl க்கு குறைவாக
    b. 80-120 mg/dl
    c. 120 mg/dl க்கு அதிகமாக
7. சிறுநீரில் ஆல்புமின் அளவு:
    a. 35 gm/L க்கு குறைவாக
    b. 35-50 gm/L
    c. 50 gm/L க்கு அதிகமாக

கால் வீக்கத்திற்கான காரணங்கள் மற்றும் அதன் மேலான்மையை மதிப்பிடுதல்

1. குடும்பத்தில் யாருக்கேனும் பின்வரும் நோய் உள்ளதா?
    a. சர்க்கரை நோய்
    b. உயர் இரத்த அழுத்தம்
    c. இருதய நோய்
    d. ஏதுமில்லை
2. இதற்கு முன்பு பிரசவத்தின் போது கால் வீக்கம் ஏற்பட்டதுண்டா?
    a. ஆம்
    b. இல்லை

3. நீண்ட நேரம் (4 மணி நேரத்திற்கு மேல்) அமர்ந்திருப்பதுண்டா?
    a. ஆம்
    b. இல்லை
4. நீண்ட நேரம் (4 மணி நேரத்திற்கு மேல்) நிற்பதுண்டா?
    a. ஆம்
    b. இல்லை
5. இறுக்கமான காலுறைகளை அணிவதுண்டா?
    a. ஆம்
    b. இல்லை
6. எந்த விதமான காலணிகளை அணிவீர்கள்?
    a. சமமான காலணிகள்
    b. சிறிய ஹீல் வைத்த காலணிகள்
    c. ஷீ
    d. வேறு ஏதேனும் _____
7. மதிய வேளையில் இளைப்பாறும் நேரத்தின் அளவு?
    a. இரண்டு மணி நேரம்
    b. இரண்டு மணி நேரத்திற்கு மேல்
    c. இரண்டு மணி நேரத்திற்கும் குறைவாக
8. எவ்விதமான நிலையில் உறங்குவீர்கள்?
    a. இடது புறமாக
    b. வலது புறமாக
    c. இடது மற்றும் வலதுபுறமாக
    d. நேராக
9. எந்த நேரத்தில் கால் வீக்கம் அதிகரிக்கும்?
    a. காலை
    b. மதியம்
    c. மாலை
    d. இரவு
10. தினமும் பயணம் செய்வீர்களா?
    a. ஆம்
    b. இல்லை
11. உணவு பழக்க வழக்கங்கள்
    a. சைவம்
    b. அசைவம்
    c. இரண்டும்

12.காபி அருந்தும் பழக்கம் உண்டா?

a. ஆம்
b. இல்லை

ஆம் எனில் ஒரு நாளில் எத்தனை முறை _____

13.தினமும் எவ்வளவு தண்ணீர் அருந்துவீர்கள்?

a. 1 லிட்டருக்கும் குறைவாக
b. 1-2 லிட்டர்
c. 2-3 லிட்டர்
d. 3 லிட்டருக்கும் மேல்

14.உணவிற்கு எடுத்துக்கொள்ளும் உப்பின் அளவு?

a. குறைவாக
b. அளவாக
c. அதிகமாக

15.கால் வீக்கத்தை குறைப்பதற்காக ஏதேனும் யுத்திகளை கடைபிடிக்கிறீர்களா?

a. கால்களை உயர்த்திவைத்தல்
b. இறுக்கமான காலுறைகளை அணிதல்
c. வெளியே செல்வதை தவிர்த்தல்
d. எண்ணெய் தடவுதல் / ஐஸ் கட்டி ஒத்தடம் கொடுத்தல்
e. இளகுவான பருத்தி ஆடைகளை அணிதல்
f. உடற்பயிற்சி செய்தல்
g. ஏதேனும் _____

ANNEXURE V

PROTOCOL

LEG MASSAGE TO REDUCE PHYSIOLOGICAL LOWER LEG EDEMA

DEFINITION:

It is the massaging of foot and lower leg in circular motion to reduce physiological lower leg edema among antenatal mothers from 3rd trimester. It manipulates superficial and deeper layers of muscle and connective tissues of the limbs.

PURPOSE:

- To provide comfort
- To promote relaxation
- To reduce physiological lower leg edema
- To reduce hospital stay

INTERVENTIONS:

- Explain the procedure and its purpose to the sample.
- Provide privacy
- Place the mother in supine position. Leg massage is given specifically targeting the muscles in the foot and lower leg for 20 minutes.
- Spread oil on the feet and lower leg and rub the oil from the heels to the lower leg.
- Hold the heel in one hand and start rotating the toe in a gentle motion, four times clockwise and four times anti-clockwise. Using the finger pads massage the top of the feet in a circular motion from toes to ankle.
- Perform internal rotation, external rotation and plantar flexion 3 times each respectively by holding the feet.
- Using the fingers, massage the toes completely.
- Massage with gentle stroke along the feet and leg with the finger pads towards the heart and in circular motion on the joints including patellar and popliteal surface.
- The post test degree of edema was assessed 6 hours (after the intervention of leg massage was given) by using modified Erwin edema scale.

ANNEXURE-VI

MASTER CODING SHEET

S.no	Education	Occupation	Type of family	Area of living	Height	Weight	BMI	Obstetric score	Blood pressure	Sodium level	Hb level	Blood glucose level	urine albumin	Family history	previous lower leg edema	Prolonged sitting	Prolonged standing	Wearing tight stockings	Type of footwear	Hours of rest	Position during sleep	Timing of severity	Travel daily	Dietary habits	Coffee intake	Water intake	Salt intake	Measures to reduce edema
1	4	1	1	1	3	3	3	1	4	2	2	2	1	4	1	2	2	2	1	3	1	3	2	3	2	3	2	6
2	4	2	1	1	4	4	3	1	1	1	3	2	1	2	1	1	1	2	1	3	3	4	1	3	1	3	2	5
3	4	2	2	1	3	3	3	2	2	2	3	2	1	4	2	1	2	2	1	3	2	3	1	3	1	2	2	1
4	4	1	1	1	4	3	3	1	4	1	3	2	1	1	2	1	2	2	1	3	2	3	2	3	2	3	1	1
5	4	1	1	1	2	2	3	2	1	1	3	2	1	4	1	2	2	2	1	3	3	1	2	3	2	3	2	1
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